allow the cultivation of mammalian cells under optimal conditions, even if grown in large scale volumes and therefore allow a process performance and product quality independent of the size of the single-use bioreactor.

[0025] It is also an object of the present disclosure to provide single-use bioreactors with proportions that can be scaled from laboratory scale to industry scale bioreactors and vice versa. The design of the single-use bioreactors according to the present disclosure has this flexibility because it maintains geometric similarity.

[0026] In general, the present disclosure is directed to a bioreactor system and method. The present disclosure is also directed to a single use bioreactor that is well suited to incubating cell cultures and thereafter being disposed. The single use bioreactor of the present disclosure can be scaled to any suitable size and is designed to fit in pre-existing stainless steel structures. The bioprocess system and method of the present disclosure contain many unique aspects and features.

[0027] According to the disclosure, a single-use bioreactor is provided. The single-use bioreactor may include a bioprocess container, a shell, at least one agitator, at least one sparger, at least one gas filter inlet port for the sparger(s) and headspace overlay, at least one fill port, at least one harvest port, at least one sample port, and at least one probe.

[0027a] According to one aspect, there is provided a bioreactor comprising:
a bioprocess container made from a liquid impermeable and flexible shape-conforming material, the bioprocess container having a top, a bottom, and at least one side wall therebetween, the bioprocess container defining a hollow enclosure for receiving a culture media; and
a mixing device comprising a rotatable shaft coupled to at least one top impeller and at least one bottom impeller that extend into the hollow enclosure of the bioprocess container, the top impeller and the bottom impeller both being made from a polymer material, wherein the polymer material of the top impeller and the bottom impeller include a hydrophilic surface; and wherein the flexible shape-conforming material comprises a multi-layered film, the multi-layered film including an interior surface facing the hollow enclosure and an opposite exterior surface, the interior surface has been modified to form a hydrophilic surface.

[0027b] According to another aspect, there is provided a bioreactor comprising:

a bioprocess container made from a liquid impermeable and flexible shape-conforming material, the bioprocess container having a top, a bottom, and at least one side wall therebetween, the bioprocess container defining a hollow enclosure for receiving a culture media;

at least one inlet port for feeding materials into the hollow enclosure of the bioprocess container;

a mixing device comprising a rotatable shaft coupled to at least one agitator, the shaft and agitator extending into the hollow enclosure of the bioprocess container; and

at least one baffle being configured to extend adjacent to the side wall of the bioprocess container in a longitudinal direction, the baffle having a shape that extends radially inward from the side wall an amount sufficient to affect fluid flow in the hollow enclosure during mixing of a culture media by the mixing device; wherein the flexible shape-conforming material comprises a multi-layered film, the multi-layered film including an interior surface facing the hollow enclosure and an opposite exterior surface, the interior surface has been modified to form a hydrophilic surface.

[0028] In one embodiment, the present disclosure is directed to a bioreactor comprising a bioprocess container. The bioprocess container is made from a liquid impermeable and flexible shape-conforming material. For instance, the bioprocess container can be made from a flexible film, such as a multi-layer film. In one embodiment, for instance, the film is comprised of a polyethylene polymer, such as a low density polyethylene that has been modified to form a hydrophilic surface. The hydrophilic surface is for contact with cell cultures within the bioreactor and improves wettability. In one embodiment, the polyethylene polymer is modified by being subjected to irradiation, photo or plasma induction, or oxidation.

[0029] The bioprocess container can have a top, a bottom, and at least one side wall therebetween. The bioprocess chamber can define a hollow enclosure for receiving a culture media. The hollow enclosure can have any suitable volume, such as 100 mL, 250 mL, 500 mL, 750 mL, 1 liter, 2 liters, 3 liters, 4 liters, 5 liters, 6 liters, 7 liters, 8 liters, 9

CLAIMS

1. A bioreactor comprising:

a bioprocess container made from a liquid impermeable and flexible shape-conforming material, the bioprocess container having a top, a bottom, and at least one side wall therebetween, the bioprocess container defining a hollow enclosure for receiving a culture media; and

a mixing device comprising a rotatable shaft coupled to at least one top impeller and at least one bottom impeller that extend into the hollow enclosure of the bioprocess container, the top impeller and the bottom impeller both being made from a polymer material, wherein the polymer material of the top impeller and the bottom impeller include a hydrophilic surface; and wherein the flexible shape-conforming material comprises a multi-layered film, the multi-layered film including an interior surface facing the hollow enclosure and an opposite exterior surface, the interior surface has been modified to form a hydrophilic surface.

2. A bioreactor as defined in claim 1, wherein the impeller to tank diameter ratio is from 0.35 to 0.55.

3. A bioreactor as defined in claim 1, wherein the impeller to tank diameter ratio is 0.44 to 0.46.

4. A bioreactor as defined in any of the preceding claims, wherein the top impeller flow number (N_q) is from 0.4 to 0.9.

5. A bioreactor as defined in any of the preceding claims, wherein the bottom impeller flow number (N_q) is from 0.4 to 0.9.

6. A bioreactor as defined in claim 1, further comprising at least one baffle being configured to extend adjacent to the side wall of the bioprocess container in a longitudinal direction, the baffle having a shape that extends radially inward from the side wall an amount sufficient to affect fluid flow in the hollow enclosure during mixing of a culture media by the mixing device.

7. A bioreactor comprising:

a bioprocess container made from a liquid impermeable and flexible shape-conforming material, the bioprocess container having a top, a bottom, and at least one side wall therebetween, the bioprocess container defining a hollow enclosure for receiving a culture media;

at least one inlet port for feeding materials into the hollow enclosure of the bioprocess container;

a mixing device comprising a rotatable shaft coupled to at least one agitator, the shaft and agitator extending into the hollow enclosure of the bioprocess container; and

at least one baffle being configured to extend adjacent to the side wall of the bioprocess container in a longitudinal direction, the baffle having a shape that extends radially inward from the side wall an amount sufficient to affect fluid flow in the hollow enclosure during mixing of a culture media by the mixing device; wherein the flexible shape-conforming material comprises a multi-layered film, the multi-layered film including an interior surface facing the hollow enclosure and an opposite exterior surface, the interior surface has been modified to form a hydrophilic surface.

8. A bioreactor as defined in claim 7, wherein the agitator comprises an impeller.

9. A bioreactor as defined in claim 8, wherein the bioreactor includes a first impeller and a second impeller, the impellers being spaced along the rotatable shaft.

10. A bioreactor as defined in any of claims 7 to 9, wherein the shape-conforming material of the bioprocess container comprises a flexible film.

11. A bioreactor as defined in claim 10, wherein the flexible film comprises a multi-layered film, the multi-layered film including an interior surface facing the hollow enclosure and an opposite exterior surface, the interior surface has been modified to form a hydrophilic surface.

12. A bioreactor as defined in any of claims 6 to 11, wherein the baffle defines an inflatable fluid bladder, the baffle being capable of being inflated and deflated.

13. A bioreactor as defined in any of claims 6 to 12, wherein the baffle is configured to be placed outside the hollow enclosure and wherein the side wall of the bioprocess container conforms around the shape of the baffle.

14. A bioreactor as defined in any of claims 6 to 13, wherein the bioreactor includes from about two to about six baffles, the baffles being spaced around a circumference of the hollow enclosure of the bioprocess container.

15. A bioreactor as defined in any of any of claims 6 to 14, wherein the bioprocess container has a diameter and wherein the baffle extends radially inward a

distance of from 3% to 20%, such as from 5% to 15% of the diameter of the bioprocess container.

16. A bioreactor as defined in any one of the preceding claims, wherein the bioreactor further comprises at least one sparger.

17. A bioreactor as defined in claim 16, wherein the sparger comprises a ballast sparger, the ballast sparger comprising a gas tube that has a longitudinal portion and a lateral portion, the longitudinal portion extending vertically into the hollow enclosure of the bioprocess container, the lateral portion being located at an end of the longitudinal portion below an agitator, the lateral portion defining a plurality of holes for releasing a gas into a culture media contained within the bioprocess container.

18. A bioreactor as defined in any of the preceding claims, further comprising at least one feed line that extends into the hollow enclosure for feeding fluids into the bioprocess container, the feed line including a subsurface fluid outlet positioned adjacent of an agitator, the fluid outlet being associated with a fluid control device that only permits fluid to flow out of the fluid outlet and prevents fluid flow in an opposite direction.

19. A bioreactor as defined in any of the preceding claims, further comprising at least one feed line positioned at the top of the bioprocess container, the feed line including a supersurface fluid discharge positioned above a volume of culture media residing in the bioprocess container, the supersurface fluid discharge being located such that a fluid flowing through the fluid discharge makes direct contact with a culture media contained within the bioprocess container.

20. A bioreactor as defined in claim 19, wherein the top impeller or agitator forms a circumference when rotated and wherein the supersurface fluid discharge of the feed line is positioned above the circumference of the top impeller or agitator such that fluids flowing through the fluid discharge contact the culture media within the circumference.

21. A bioreactor as defined in any of the preceding claims, wherein the bioprocess container is in fluid communication with a drain line located at the bottom of the bioprocess container, and wherein a fluid collecting device is positioned inbetween the hollow enclosure of the bioprocess container and the drain line, the fluid collecting device having a shape configured to induce a vortex flow of fluids from the bioprocess container into the drain line.

22. A bioreactor as defined in claim 21, wherein the hollow enclosure of the bioprocess container has a volume and wherein the drain line has a cross-sectional area and wherein the cross-sectional area of the drain line is proportional to the volume of the hollow enclosure, the drain line having a cross-sectional area of from 0.3 mm^2 to 0.7 mm^2 per liter of volume of the hollow enclosure.