SUMMARY OF THE INVENTION

In accordance with the instant invention, an ~~extracorporeal membrane oxygenation system (artificial placenta)~~incubation apparatus for maintaining a fetus in an extrauterine setting to allow for growth and maturation is provided. In a particular embodiment, the ~~system is pumpless and~~apparatus comprises ~~a very low resistance oxygenator~~an incubation chamber for holding a volume of liquid so that the fetus can be submerged in the liquid in the incubation chamber. The incubation chamber comprises an inlet port for pumping in sterile liquid and an exit port for the removal of used liquid. The ~~system/~~apparatus ~~may~~ further comprise~~s an incubation chamber for holding the subject and sterile liquid in which to submerge the subject~~a pumpless oxygenation circuit comprising a low resistance oxygenator having an inflow port and an outflow port. The circuit provides arterial outflow from the fetus under pulsatile systemic pressure connected to the oxygenator inflow port and return flow connected to the outflow port. The ~~system/~~apparatus ~~may~~ further comprise~~s~~ means for pumping liquid to provide a flow of sterile liquid through the incubation chamber. The flow enters through the inlet port and drains through the outlet port.~~a pump and filtration system for the sterile liquid. Examples of a system/apparatus of the instant invention are shown in Figures 1 and 7A.~~

In accordance with another aspect of the instant invention, ~~methods for the extracorporeal oxygenation of a subject (e.g., maintaining a fetus in an extrauterine setting to allow for growth and maturation)~~an incubation apparatus for maintaining a fetus in an extrauterine setting to allow for growth and maturation is~~are~~ provided. In a particular embodiment, the ~~method~~ apparatus comprises ~~connecting the subject to the extracorporeal membrane oxygenation system of the instant invention~~an incubation chamber for holding a volume of liquid so that the fetus can be submerged in the liquid in the incubation chamber. ~~The subject may be connected to the oxygenator via vessels in the neck. In a particular embodiment, the subject is a premature fetus, extreme premature fetus, or a pre-viable fetus. In a particular embodiment, the oxygenator is primed with fetal blood. The subject may also be maintained submerged in an incubation chamber comprising sterile liquid, particularly where the sterile liquid is heated and continually pumped through a filtration system~~The apparatus further comprises a pumpless oxygenation circuit comprising a low resistance oxygenator having an inflow port and an outflow port. The circuit provides arterial outflow from the fetus under pulsatile systemic pressure connected to the

oxygenator inflow port and return flow connected to the outflow port. The oxygenator is positioned outside the liquid in the incubation chamber.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 provides a photo of an example of an apparatus of the instant invention.

Figure 2 provides a photo of an example of the incubation chamber. Four ports in the chamber are clearly identified. Two of the ports are for circulation of the sterile liquid in the chamber (labeled "amniotic in" and "amniotic out"). The other two ports are for circulating warm liquid into an enclosed unit within the chamber to maintain the subject's body temperature.

Figure 3 provides a photo of an example of a dry chamber comprising an oxygenator.

Figure 4 provides a photo of a filtration system.

Figure 5 provides a photo of a circuit design with the oxygenator.

Figure 6A provides a photo of a premature lamb connected to the apparatus of the instant invention. Figure 6B provides a photo of the lamb after 5 days of growth.

What is claimed is:

1. A method for the extracorporeal oxygenation of a subject, said method comprising connecting the circulatory system of the subject to an extracorporeal membrane oxygenation system, wherein said extracorporeal membrane oxygenation system is pumpless and comprises a very low resistance oxygenator.

2. The method of claim 1, wherein said oxygenator has a pressure drop of less than about 40 mmHg at 1.5 L/min of blood flow.

3. The method of claim 1, wherein said oxygenator is the Quadrox-iD™ pediatric oxygenator.

4. The method of claim 1, wherein said subject is a premature fetus, extreme premature fetus, or a pre-viable fetus.

5. The method of claim 1, wherein said oxygenator is primed with fetal blood.

6. The method of claim 1, wherein said subject is maintained submerged in an incubation chamber comprising sterile liquid.

7. The method of claim 1, wherein said incubation chamber is heated to maintain the body temperature of the subject.

8. The method of claim 6, wherein the sterile liquid is pumped through a filtration system.

9. The method of claim 6, wherein the subject is administered nutritional support intravenously while in the incubation chamber.

10. An incubation apparatus comprising an extracorporeal membrane oxygenation system and an incubation chamber, wherein said extracorporeal membrane oxygenation system is pumpless and comprises a very low resistance oxygenator.

11. The apparatus of claim 10, wherein said oxygenator has a pressure drop of less than about 40 mmHg at 1.5 L/min of blood flow.

12. The apparatus of claim 10, wherein said oxygenator is the Quadrox-iD™ pediatric oxygenator.

13. The apparatus of claim 10, wherein the incubation chamber is connected to a pump and at least one filter.

14. The apparatus of claim 10, wherein the incubation chamber is connected to a UV fluid filter.

15. The apparatus of claim 10, wherein said incubation chamber comprises glove ports.

16. The apparatus of claim 10, wherein sid incubation chamber comprises at least one inlet and at least one outlet.

What is claimed is:

1. An incubation apparatus for maintaining a fetus in an extrauterine setting to allow for growth and maturation, comprising:

an incubation chamber for holding a volume of liquid so that the fetus can be submerged in the liquid in the incubation chamber;

wherein the incubation chamber comprises an inlet port for pumping in sterile liquid and an exit port for the removal of used liquid;

a pumpless oxygenation circuit comprising:

an low resistance oxygenator having an inflow port and an outflow port;

wherein the circuit provides arterial outflow from the fetus under pulsatile systemic pressure connected to the oxygenator inflow port and return flow connected to the outflow port;

means for pumping liquid to provide a flow of sterile liquid through the incubation chamber, wherein the flow enters through the inlet port and drains through the outlet port.

2. The incubation apparatus of claim 1 wherein the means for pumping pumps sterile liquid through the inlet port and discharges fluid from the outlet port to exchange the used liquid in the chamber with sterile liquid.

3. The incubation apparatus of claim 1 wherein the oxygenator has a pressure drop of less than 40 mmHg at 1.5 l/min of blood flow.

4. The incubation apparatus of claim 1 wherein the oxygenator is outside the liquid in the incubation chamber.

5. The incubation apparatus of claim 1 wherein the pumpless oxygenation circuit permits innate hemodynamics to be maintained by autoregulation.

6. The incubation apparatus of claim 1 wherein the pumpless oxygenation circuit provides blood flow of about 2.0 l/min or greater.

7. The incubation apparatus of claim 1 wherein the incubation chamber is sealed to prevent contamination of the liquid in the chamber.

8. The incubation apparatus of claim 1 wherein the incubation chamber comprises a bag or sac.

9. The incubation apparatus of claim 8 wherein the bag or sac comprises inert medical grade plastic or silicone.

10. The incubation apparatus of claim 1 comprising suction means to permit removal of waste products and debris from the liquid in the chamber.

11. The incubation apparatus of claim 1 wherein the chamber comprises glove ports to allow sterile access to the fetus while the fetus is in the liquid.

12. The incubation apparatus of claim 1 wherein the liquid in the chamber comprises synthetic amniotic liquid.

13. The incubation apparatus of claim 1 comprising a gas mixer for blending a mixture of air and oxygen to form a sweep gas, wherein the sweep gas is connected with the oxygenator.

14. The incubation apparatus of claim 1 wherein the oxygenation circuit provides gas transfer rate of about 150 ml/min or greater.

15. The incubation apparatus of claim 1 comprising means for filtering the liquid, wherein the liquid is pumped through the means for filtering and the filtered liquid is then pumped into the chamber.

16. The incubation apparatus of claim 1 comprising:

a supply tank for storing a supply of liquid greater than the volume of liquid in the incubation chamber; and

a drain for receiving used liquid from the incubation chamber;

wherein the means for pumping pumps liquid from the supply tank into the chamber and the means for pumping pumps fluid from the chamber to the drain.

17. The incubation apparatus of claim 1 wherein the chamber is a closed sterile system with continuous liquid exchange.

18. An incubation apparatus for maintaining a fetus in an extrauterine setting to allow for growth and maturation, comprising:

an incubation chamber for holding a volume of liquid so that the fetus can be submerged in the liquid in the incubation chamber;

a pumpless oxygenation circuit comprising;

an low resistance oxygenator having an inflow port and an outflow port;

wherein the circuit provides arterial outflow from the fetus under pulsatile systemic pressure connected to the oxygenator inflow port and return flow connected to the outflow port; and

wherein the oxygenator is positioned outside the liquid in the incubation chamber.

19. The incubation apparatus of claim 18 wherein the incubation chamber comprises a bag or sac.

20. The incubation apparatus of claim 19 wherein the bag or sac comprises inert medical grade plastic or silicone.

21. The incubation apparatus of claim 18 comprising suction means to permit removal of waste products and debris from the liquid in the chamber.

22. The incubation apparatus of claim 18 wherein the chamber comprises glove ports to allow sterile access to the fetus while the fetus is in the liquid.

23. The incubation apparatus of claim 18 comprising a gas mixer for blending a mixture of air and oxygen to form a sweep gas, wherein the sweep gas is connected with the oxygenator.

24. The incubation apparatus of claim 18 comprising:

a supply tank for storing a supply of liquid greater than the volume of liquid in the incubation chamber; and

a drain for receiving used liquid from the incubation chamber;

means for pumping fluid from the supply tank into the chamber and for pumping fluid from the chamber to the drain;

wherein the means for pumping provides a flow of liquid through the chamber.