

WHAT IS CLAIMED IS:

1. A packaging system for storing a bioprosthetic device, wherein the packaging system maintains a target relative humidity across a temperature range, the packaging system comprising:
 - a sealed package defining an internal space having an internal volume;
 - at least one bioprosthetic device disposed within the internal space; and
 - at least one humidity control device disposed within the internal space, the humidity control device having a barrier defining an enclosed space and a humidity control solution comprising glycerol in the enclosed space;
 - wherein at least a portion of the barrier comprises a gas-permeable membrane;
 - wherein the target relative humidity is provided within the internal volume of the sealed package; and
 - wherein the humidity control device maintains the target relative humidity across the temperature range by selectively liberating and absorbing water vapor.
2. The packaging system of claim 1, wherein the gas-permeable membrane has a water vapor transfer rate of from about 3 to about 10 mg/cm² per 24 hours.
3. The packaging system of claim 1 or 2, wherein the gas-permeable membrane has a surface area, and a ratio of the surface area of the gas-permeable membrane to the internal volume of the sealed package is from about 6 to about 30 mg/mL.
4. The packaging system of any one of claims 1–3, wherein the gas-permeable membrane has an average porosity of about 8 to about 36 Gurley units.
5. The packaging system of any one of claims 1–4, wherein the gas-permeable membrane is a hydrophobic homopolymer.
6. The packaging system of claim 5, wherein the gas-permeable membrane is a high-density polyethylene having a microfibrinous structure.
7. The packaging system of claim 6, wherein the gas-permeable membrane is a medical-grade material.
8. The packaging system of any one of claims 1–7, wherein the sealed package comprises a polymer/foil pouch.

9. The packaging system of any one of claims 1–8, wherein the sealed package has a water vapor transfer rate of less than about 0.002 grams per day.
10. The packaging system of any one of claims 1–9, wherein the sealed package is hermetically sealed.
11. The packaging system of any one of claims 1–10, wherein the bioprosthetic device comprises a bioprosthetic tissue that has a reduced water content of about 25% by weight or less.
12. The packaging system of claim 11, wherein the bioprosthetic tissue is glycerolized.
13. The packaging system of claim 11, wherein the bioprosthetic device is a heart valve; and

wherein the bioprosthetic tissue forms leaflets of the heart valve.
14. The packaging system of any one of claims 1–13, wherein the packaging system maintains the target relative humidity within a tolerance of about $\pm 10\%$.
15. The packaging system of claim 14, wherein packaging system maintains the target relative humidity within a tolerance of about $\pm 5\%$.
16. A packaging system for storing a bioprosthetic device, wherein the packaging system maintains a target relative humidity across a temperature range, the packaging system comprising:

a sealed package having an internal space;

a bioprosthetic device disposed within the internal space; and

a humidity control device disposed within the internal space, the humidity control device having a barrier defining an enclosed space in vapor communication with the internal space of the sealed package and a humidity control solution comprising glycerol in the enclosed space.
17. The packaging system of claim 16, wherein the humidity control solution has a total weight, and a ratio of the total weight of the humidity control solution to an internal volume of the sealed package is at least about 6 mg/mL.

18. The packaging system of claim 16 or 17, wherein the humidity control solution releases and absorbs water vapor in response to changes in temperature, thereby maintaining the target relative humidity.

19. The packaging system of any of claims 16–18, wherein the packaging system maintains the target relative humidity across the temperature range from about –18 °C to about 45 °C.

20. The packaging system of any of claims 16–19, wherein the target relative humidity is from about 15% to about 95%.

21. The packaging system of any of claims 16–20, wherein the humidity control solution further comprises an aqueous solution, wherein the glycerol is provided in a concentration of from about 34% to about 96% (by weight) of the humidity control solution and the aqueous solution is provided in a concentration of from about 4% to about 66% (by weight) of the humidity control solution.

22. The packaging system of any of claims 16–21, wherein a concentration of the glycerol (G_w) in the humidity control solution is substantially related to the target relative humidity (RH) according to Eq. 1:

$$G_w = 383(-0.189(RH) + 19.9)^{0.0806} - 383 \quad \text{Eq. 1}$$

23. The packaging system of any of claims 16–21, wherein the target relative humidity (RH) is substantially related to a concentration of the glycerol (G_w) in the humidity control solution according to Eq. 2:

$$RH = \frac{-\left(\frac{G_w + 383}{383}\right)^{12.4} - 19.9}{0.189} \quad \text{Eq. 2}$$

24. The packaging system of any of claims 16–23, wherein the humidity control solution further comprises a microbicidal agent.

25. The packaging system of claim 24, wherein the microbicidal agent comprises glutaraldehyde.

26. The packaging system of claim 24, wherein the microbicidal agent comprises an aqueous solution comprising about 97% (by volume) water and about 3% (by volume) of a solution of about 0.625% (by weight) glutaraldehyde.

27. The packaging system of any of claims 16–26, wherein the packaging system maintains the target relative humidity within a tolerance of about $\pm 10\%$.

28. The packaging system of claim 27, wherein the packaging system maintains the target relative humidity within a tolerance of about $\pm 5\%$.

29. A method of storing one or more bioprosthetic devices within a packaging system that maintains a target relative humidity across a temperature range, the method comprising the steps of:

determining an internal volume of an outer packaging;

selecting the target relative humidity;

providing one or more humidity control devices comprising a humidity control solution disposed within an at least partially gas-permeable enclosure, the humidity control solution comprising glycerol; and

sealing the one or more humidity control devices and the one or more bioprosthetic devices within the internal volume of the outer packaging.

30. The method of claim 29, wherein selecting the target relative humidity comprises selecting a target relative humidity from about 15% to about 95%.

31. The method of claim 29 or 30, wherein a concentration of the glycerol (G_w) (by weight) in the humidity control solution is substantially related to the target relative humidity (RH) according to Eq. 1:

$$G_w = 383(-0.189(\text{RH}) + 19.9)^{0.0806} - 383 \quad \text{Eq. 1}$$

32. The method of claim 29 or 30, wherein the target relative humidity (RH) is substantially related to a concentration of the glycerol (G_w) in the humidity control solution according to Eq. 2:

$$\text{RH} = \frac{-\left(\frac{G_w + 383}{383}\right)^{12.4} - 19.9}{0.189} \quad \text{Eq. 2}$$

33. The method of any of claims 29–32, wherein a weight of the humidity control solution is at least about 6 mg/mL of the internal volume.

34. The method of any of claims 29–33, wherein the one or more humidity control devices effectively maintain the target relative humidity from about -18°C to about 45°C .

35. The method of any of claims 29–34, wherein the at least partially gas-permeable enclosure has a water vapor transfer rate of from about 3 to about 10 mg/cm² per 24 hours.

36. The method of any of claims 29–35, further comprising sterilizing the outer packaging.

37. The method of any of claims 29–36, wherein the packaging system maintains the target relative humidity within a tolerance of about $\pm 10\%$.

38. The packaging system of claim 37, wherein the packaging system maintains the target relative humidity within a tolerance of about $\pm 5\%$.