

WHAT IS CLAIMED IS:

1. An method to remove antigens and cells from a bioprosthetic tissue, comprising:
 - solubilizing hydrophilic biomolecules within a bioprosthetic tissue utilizing a reducing agent;
 - solubilizing lipophilic biomolecules within the bioprosthetic tissue utilizing at least one detergent; and
 - enzymatically degrading biomolecules within the bioprosthetic tissue utilizing at least one of: a nuclease, a lipase, a carbohydrase, or a depolymerase.
2. The method as in claim 1, wherein the reducing agent is one of: β -mercaptoethanol (BME or 2-ME), *tris*(2-carboxyethyl)phosphine (TCEP), dithiothreitol (DTT), tributylphosphine (TBP or TnBP), or a combination thereof.
3. The method as in any one of the preceding claims, wherein the at least one detergent is a nonionic detergent, a zwitterionic detergent, an ionic detergent, or a plurality of detergents comprising at least one nonionic detergent and at least one ionic detergent.
4. The method as in claim 3, wherein the zwitterionic detergent is one of: amidosulfobetaine-14 (ASB-14), amidosulfobetaine-16 (ASB-16), 4-octylbenzoylamidopropyl-dimethylammoniosulfobetaine (ASB-C80), sulfobetaine 3-10 (SB 3-10), sulfobetaine 3-12 (SB 3-12), sulfobetaine 3-14 (SB 3-14), sulfobetaine 3-16 (SB 3-16), sulfobetaine 3-18 (SB 3-18), 3-[(3-cholamidopropyl)dimethylammonio]-1-propanesulfonate hydrate (CHAPS), 3-[(3-cholamidopropyl)dimethylammonio]-2-hydroxy-1-propanesulfonate (CHAPSO), non-detergent sulfobetaine 195 (NDSB-195), non-detergent sulfobetaine 201 (NDSB-201), non-detergent sulfobetaine 211 (NDSB-211), non-detergent sulfobetaine 221 (NDSB-221), or non-detergent sulfobetaine 256 (NDSB-256).
5. The method as in claim 3, wherein the nonionic detergent is one of: a polysorbate nonionic detergent, a polyethylene oxide nonionic detergent, *n*-dodecyl- β -D-maltoside (DDM), digitonin, IGEPAL CA-630, *N,N*-bis[3-(D-gluconamido)propyl]cholamide (BigCHAP), or *N,N*-bis[3-(D-gluconamido)propyl]deoxycholamide (Deoxy Big CHAP).
6. The method as in claim 3, wherein the ionic detergent is one of: sodium dodecyl sulfate (SDS), sodium deoxycholate, sodium cholate, sarkosyl, or cetyltrimethylammonium bromide (CTAB).

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7. The method as in any one of the preceding claims, wherein the nuclease is one of: RNase A, DNase I, benzonase, or a combination thereof.

8. The method of as in any one of the preceding claims, wherein the lipase is one of: triacylglycerol lipase, pancreatic lipase, or a combination thereof.

9. The method as in any one of the preceding claims, wherein the carbohydrase is one of: amylase, arabanase, cellulose, glucanase, xylanase, or a combination thereof.

10. The method as in any one of the preceding claims, wherein the bioprosthetic tissue is animal tissue.

11. The method as in claim 10, wherein the animal tissue is one of: pericardium, heart valve, blood vessel, small intestinal submucosa, collagen-based tissue, or elastin-based tissue.

12. The method as in claim 10 or 11, wherein the animal tissue is one of: bovine, porcine, ovine, avian, or human.

13. The method as in any one of the preceding claims further comprising: removing undesirable tissue from the bioprosthetic tissue.

14. The method as in claim 13, wherein the undesirable tissue is one of: adipose, venous, cartilaginous, or a combination thereof.

15. The method as in any one of the preceding claims further comprising: fixing the bioprosthetic tissue.

16. The method as in claim 15, wherein the bioprosthetic tissue is fixed by a method selected from a group consisting of: perfusion, immersion, freezing, drying, or a combination thereof.

17. The method as in claim 15 or 16, wherein at least one crosslinking agent is used to fix the bioprosthetic tissue.

18. The method as in claim 17, wherein the at least one crosslinking agent is one of: formaldehyde, glutaraldehyde, paraformaldehyde, formalin, genipin, 1-ethyl-3-(3-dimethylaminopropyl)carbodiimide hydrochloride (EDC), or a combination thereof.

19. The method as in one of claims 17 or 18, wherein the at least one crosslinking agent comprises formaldehyde, glutaraldehyde, paraformaldehyde, or formalin, and the method further comprising:

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stabilizing aldehyde crosslinks within the bioprosthetic tissue.

20. The method as in claim 19, wherein the stabilizing aldehyde crosslinks comprises treating with heat for an extended period of time.

21. The method as in any one of claims 17–20, wherein the at least one crosslinking agent comprises formaldehyde, glutaraldehyde, paraformaldehyde, or formalin, and the method further comprising:

capping free aldehydes within the bioprosthetic tissue.

22. The method as in claim 21, wherein the capping free aldehydes comprises treating with a reducing agent, an amine, or a combination thereof.

23. The method as in any one of claims 17 or 18, wherein the at least one crosslinking agent comprises 1-ethyl-3-(3-dimethylaminopropyl)carbodiimide hydrochloride (EDC) and the method further comprising:

stabilizing carboxy crosslinks within the bioprosthetic tissue.

24. The method as in claim 23, wherein the stabilizing carboxy crosslinks comprises treating with heat for an extended period of time.

25. The method as in claim 15 or 16, wherein an enzymatic crosslinker is used to fix the bioprosthetic tissue.

26. The method as in claim 25, wherein the enzymatic crosslinker is one of: a transglutaminase, an oxidoreductase, or a combination thereof.

27. The method as in one of claims 15 or 16, wherein a precipitating agent is used to fix the bioprosthetic tissue.

28. The method as in claim 27, wherein the precipitating agent is one of: methanol, ethanol, propanol, acetone, or a combination thereof.

29. The method as in any one of the preceding claims further comprising: capping free carboxyl groups within the bioprosthetic tissue.

30. The method as in claim 29, wherein the capping free carboxyl groups comprises treating with 1-ethyl-3-(3-dimethylaminopropyl)carbodiimide hydrochloride (EDC).

31. The method as in any one of the preceding claims further comprising: performing a bioburden reduction treatment on the bioprosthetic tissue.

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32. The method as in claim 31, wherein the bioburden reduction treatment comprises one of: treatment with cytotoxic reagents, treatment with antimicrobial agents, heat treatment, pressure treatment, radiation treatment, treatment with a detergent, treatment with a crosslinking agent, or a combination thereof.

33. The method as in any one of the preceding claims further comprising: storing the bioprosthetic tissue within a solution.

34. The method as in claim 33, wherein the solution is a fixation buffer or propylene oxide in water.

35. The method as in any one of the preceding claims further comprising: treating the bioprosthetic tissue with a solution for dry storage.

36. The method as in claim 35, wherein the solution for dry storage comprises a glycerol, polyethylene glycol, or a saccharide.

37. The method as in claim 35, wherein the solvent for the solution for dry storage is aqueous based or alcohol based.

38. The method as in claim 35, wherein glycerolization is performed as the treatment of the bioprosthetic tissue for dry storage.

39. The method as in claim 38, wherein the solution for dry storage comprises a percentage of glycerol selected from about: 50%, 60%, 70%, 80%, 90%, or 100%.

40. The method as in claim 38 or 39, wherein the solution for dry storage comprises a percentage of C₁–C₃ alcohol selected from about: 0%, 10%, 20%, 30%, 40%, or 50%.

41. The method as in any one of the preceding claims further comprising: sterilizing the bioprosthetic tissue.

42. The method as in claim 41, wherein the sterilizing comprises a treatment selected from the group consisting of: gamma irradiation, gas plasma, aldehydes, ethylene oxide, e-beam, computerized tomography scan, and a combination thereof.

43. The method as in any one of the preceding claims further comprising: shaping the bioprosthetic tissue.

44. The method as in claim 43, wherein the shaping comprises one of: die cutting, laser cutting, folding, forming, and a combination thereof.

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45. The method as in any one of the preceding claims, wherein the bioprosthetic tissue is utilized in the manufacture of a medical device.

46. The method of claim 45, wherein the medical device is one of: a tissue patch, a medical vessel, a conduit, a closure device, or a heart valve.

47. The method of claim 45, wherein the medical device is a heart valve and the prosthetic tissue is utilized to form leaflets.