

CLAIMS

What is claimed is:

1. A seamless prosthetic valve, comprising:
a continuous tubular member having an outer abluminal surface, first and second ends, a triple walled intermediate portion, and at least a first valve leaflet, said first valve leaflet being configured to selectively restrict fluid flow through said seamless prosthetic valve, said triple walled intermediate portion being formed by everting said first end of said tubular member over said tubular member to form a double walled first end and a doubled wall portion proximal to and extending from said double walled end, and reverting said first end of said tubular member over said double walled end of said tubular member, said first valve leaflet being formed by suturing said triple walled intermediate portion at a first commissure connection point.
2. The prosthetic valve of Claim 1, wherein said triple walled intermediate portion is sutured at two commissure connection points, and wherein said first valve leaflet and a second valve leaflet are formed.
3. The prosthetic valve of Claim 1, wherein said triple walled intermediate portion is sutured at three commissure connection points, and wherein said first valve leaflet, and second and third valve leaflets are formed.
4. The prosthetic valve of Claim 1, wherein said tubular member comprises an extracellular matrix (ECM) material derived from a mammalian tissue source.
5. The prosthetic valve of Claim 4, wherein said tissue source comprises small intestine submucosa.
6. The prosthetic valve of Claim 5, wherein said small intestine submucosa comprises porcine small intestine submucosa.
7. The prosthetic valve of Claim 4, wherein said ECM material includes an additional biologically active agent.
8. The prosthetic valve of Claim 7, wherein said biologically active agent is selected from the group consisting of human embryonic stem cells, fetal cardiomyocytes, myofibroblasts, mesenchymal stem cells, autotransplanted expanded cardiomyocytes, adipocytes, totipotent cells, pluripotent cells, blood stem cells, myoblasts, adult stem cells,

bone marrow cells, mesenchymal cells, embryonic stem cells, parenchymal cells, epithelial cells, endothelial cells, mesothelial cells, fibroblasts, osteoblasts, chondrocytes, exogenous cells, endogenous cells, stem cells, hematopoietic stem cells, bone-marrow derived progenitor cells, myocardial cells, skeletal cells, fetal cells, undifferentiated cells, multi-potent progenitor cells, unipotent progenitor cells, monocytes, cardiac myoblasts, skeletal myoblasts, macrophages, capillary endothelial cells, xenogenic cells, allogenic cells, and post-natal stem cells

9. The prosthetic valve of Claim 7, wherein said biologically active agent comprises a growth factor selected from the group consisting of a platelet derived growth factor (PDGF), epidermal growth factor (EGF), transforming growth factor alpha (TGF-alpha), transforming growth factor beta (TGF-beta), fibroblast growth factor - 2 (FGF-2), basic fibroblast growth factor (bFGF), vascular epithelial growth factor (VEGF), hepatocyte growth factor (HGF), insulin-like growth factor (IGF), nerve growth factor (NGF), platelet derived growth factor (PDGF), tumor necrosis factor alpha (TNA-alpha), and placental growth factor (PLGF).

10. The prosthetic valve of Claim 4, wherein said ECM material includes an additional pharmacological agent.

11. The prosthetic valve of Claim 10, wherein said pharmacological agent comprises an anti-inflammatory.

12. The prosthetic valve of Claim 10, wherein said pharmacological agent comprises a statin.

13. The prosthetic valve of Claim 12, wherein said statin is selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin and simvastatin.

14. The prosthetic valve of Claim 10, wherein said pharmacological agent comprises an anti-arrhythmic agent.

15. The two-piece valve of Claim 14, wherein said anti-arrhythmic agent is selected from the group comprising quinidine, procainamide, disopyramide, lidocaine, phenytoin, mexiletine, flecainide, propafenone, moricizine, propranolol, esmolol, timolol,

metoprolol, atenolol, amiodarone, sotalol, ibutilide, dofetilide, verapamil, diltiazem, adenosine and digoxin.

What is claimed is:

1. A prosthetic valve, comprising:

a continuous tubular structure having an inner lumen, outer abluminal surface, first and second ends, a triple walled intermediate portion, and first and second valve leaflets, said tubular structure comprising extracellular matrix (ECM) from a mammalian tissue source,

said first and second valve leaflets being configured to transition from a first position, wherein fluid flow in a first direction through said prosthetic valve is unrestricted, to a second position, wherein fluid flow in a second direction through said prosthetic valve is restricted,

said triple walled intermediate portion being formed by everting said first end of said tubular structure over said tubular structure to form a double walled first end and a doubled wall portion proximal to and extending from said double walled end, and reverting said first end of said tubular structure over said double walled end of said tubular structure,

said first and second valve leaflets being formed in said tubular structure lumen by all three walls of suturing said triple walled intermediate portion at two commissure connection lines, wherein said first and second valve leaflets comprise two restrained regions and two unrestrained regions.

2. The prosthetic valve of claim 1, wherein said triple walled intermediate portion is sutured at a third commissure connection line, wherein a third valve leaflet is formed, and wherein said third valve leaflet comprises a third restrained region and a third unrestrained region.

3. The prosthetic valve of claim 1, wherein said ECM comprises small intestine submucosa.

4. The prosthetic valve of claim 1, wherein said ECM includes an exogenously added biologically active agent.

5. The prosthetic valve of claim 4, wherein said biologically active agent comprises a growth factor selected from the group consisting of transforming growth factor alpha (TGF-alpha), transforming growth factor beta (TGF-beta), fibroblast growth factor-2 (FGF-2), basic fibroblast growth factor (bFGF), and vascular epithelial growth factor (VEGF).

6. The prosthetic valve of claim 1, wherein said ECM includes an exogenously added pharmacological agent.

7. The prosthetic valve of claim 6, wherein said pharmacological agent comprises a statin selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin and simvastatin.

8. The prosthetic valve of claim 6, wherein said pharmacological agent comprises an anti-arrhythmic agent selected

from the group consisting of quinidine, procainamide, disopyramide, lidocaine, phenytoin, mexiletine, flecainide, propafenone, moricizine, propranolol, esmolol, timolol, metoprolol, atenolol, amiodarone, sotalol, ibutilide, dofetilide, verapamil, diltiazem, adenosine and digoxin.

9. A prosthetic valve, comprising:

a continuous tubular structure having an inner lumen, outer abluminal surface, first and second ends, a triple walled intermediate portion, and first and second valve leaflets, said tubular structure comprising acellular small intestine submucosa (SIS), said SIS comprising less than 4% DNA content and a dry weight bFGF content of at least 140 pg/mg of said SIS, said SIS further exhibiting at least 96% decellurization and a tensile strength of at least 9 N,

said first and second valve leaflets being configured to transition from a first position, wherein fluid flow in a first direction through said prosthetic valve is unrestricted, to a second position, wherein fluid flow in a second direction through said prosthetic valve is restricted,

said triple walled intermediate portion being formed by everting said first end of said tubular structure over said tubular structure to form a double walled first end and a doubled wall portion proximal to and extending from said double walled end, and reverting said first end of said tubular structure over said double walled end of said tubular structure,

said first and second valve leaflets being formed in said tubular structure lumen by all three walls of suturing said triple walled intermediate portion at two commissure connection lines, wherein said first and second valve leaflets comprise two restrained regions and two unrestrained regions.

10. The prosthetic valve of claim 9, wherein said ECM includes an exogenously added biologically active agent.

11. The prosthetic valve of claim 10, wherein said biologically active agent comprises a growth factor selected from the group consisting of transforming growth factor alpha (TGF-alpha), transforming growth factor beta (TGF-beta), fibroblast growth factor-2 (FGF-2), basic fibroblast growth factor (bFGF), and vascular epithelial growth factor (VEGF).

12. The prosthetic valve of claim 9, wherein said ECM includes an exogenously added pharmacological agent.

13. The prosthetic valve of claim 12, wherein said pharmacological agent comprises a statin selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin and simvastatin.

14. A prosthetic valve, comprising:

a continuous tubular structure having an inner lumen, outer abluminal surface, first and second ends, a triple walled intermediate portion, and first and second valve leaflets, said tubular structure comprising mesothelial tissue from a mammalian tissue source,

said first and second valve leaflets being configured to transition from a first position, wherein fluid flow in a first direction through said prosthetic valve is unrestricted, to a second position, wherein fluid flow in a second direction through said prosthetic valve is restricted,

said triple walled intermediate portion being formed by everting said first end of said tubular structure over said tubular structure to form a double walled first end and a doubled wall portion proximal to and extending from said double walled end, and reverting said first end of said tubular structure over said double walled end of said tubular structure,

said first and second valve leaflets being formed in said tubular structure lumen by all three walls of suturing said triple walled intermediate portion at two commissure connection lines, wherein said first and second valve leaflets comprise two restrained regions and two unrestrained regions.

15. A prosthetic valve, comprising:

a continuous tubular structure having an inner lumen, outer abluminal surface, first and second ends, a triple walled intermediate portion, and first, second and third valve leaflets, said tubular structure comprising mesothelial tissue from a mammalian tissue source,

said first, second and third valve leaflets being configured to transition from a first position, wherein fluid flow in a first direction through said prosthetic valve is unrestricted, to a second position, wherein fluid flow in a second direction through said prosthetic valve is restricted,

said triple walled intermediate portion being formed by everting said first end of said tubular structure over said tubular structure to form a double walled first end and a doubled wall portion proximal to and extending from said double walled end, and reverting said first end of said tubular structure over said double walled end of said tubular structure,

said first, second and third valve leaflets being formed in said tubular structure lumen by all three walls of suturing said triple walled intermediate portion at three commissure connection lines, wherein said first, second and third valve leaflets comprise three restrained regions and three unrestrained regions.