CLAIMS

What is claimed is:

1. An intra-myocardial agent delivery device, comprising:

a myocardial tissue access line that is configured to receive a first pharmacological agent therein and provide direct fluid access of said first pharmacological agent to first myocardial tissue, and at least a first agent delivery line having a wall and a central lumen therethrough, said first agent delivery line being in fluid communication with said tissue access line,

said first agent delivery line further including a plurality of dispersal lumens extending through said delivery line wall and in fluid communication with said central lumen, wherein, when said first agent delivery line is disposed in said first myocardial tissue and said first pharmacological agent is introduced into said tissue access line, said plurality of dispersal lumens allow said first pharmacological agent to be transferred from said central lumen to said first myocardial tissue.

2. The agent delivery device of Claim 1, wherein said device includes a plurality of said first agent delivery lines.

3. The agent delivery device of Claim 1, wherein said device includes an external pump, said pump being in fluid communication with said tissue access line and configured to introduce said first pharmacological agent into said tissue access line with a first fluid pressure.

4. The agent delivery device of Claim 1, wherein said first pharmacological agent is selected from the group consisting of antibiotics or antifungal agents, anti-viral agents, anti-pain agents, anesthetics, analgesics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, anti-neoplastics, anti-spasmodics, modulators of cell-extracellular matrix interactions, proteins, hormones, growth factors, matrix metalloproteinases (MMPS), enzymes and enzyme inhibitors, anticoagulants and/or antithrombic agents, DNA, RNA, modified DNA and RNA, NSAIDs, inhibitors of DNA, RNA or protein synthesis, polypeptides, oligonucleotides, polynucleotides, nucleoproteins, compounds modulating cell migration, compounds modulating proliferation and growth of tissue, and vasodilating agents.

5. The agent delivery device of Claim 1, wherein said first pharmacological agent is selected from the group consisting of antihypertensive agents, inotropic agents, antiatherogenic agents, beta-blockers, sympathomimetic agents, phosphodiesterase inhibitors, diuretics, vasodilators, thrombolytic agents, cardiac glycosides, and antineoplastic agents.

6. The agent delivery device of Claim 1, wherein said first pharmacological agent comprises an anti-arrhythmic agent selected from the group consisting of Class I, II, III and IV anti-arrhythmic agents.

7. The agent delivery device of Claim 1, wherein said first pharmacological agent comprises a statin selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin.

8. The agent delivery device of Claim 1, wherein said first pharmacological agent comprises an antibiotic selected from the group consisting of aminoglycosides, cephalosporins, chloramphenicol, clindamycin, erythromycins, fluoroquinolones, macrolides, azolides, metronidazole, penicillins, tetracyclines, trimethoprim-sulfamethoxazole and vancomycin.

9. The agent delivery device of Claim 1, wherein said first pharmacological agent comprises a growth factor selected from the group consisting of platelet derived growth factor (PDGF), epidermal growth factor (EGF), transforming growth factor-α (TGF-α), transforming growth factor-β (TGF-β), 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), platlet derived growth factor (PDGF), tumor necrosis factor-α (TNA-α), and placental growth factor (PLGF).

10. The agent delivery device of Claim 1, wherein said first pharmacological agent comprises a steroid selected from the group consisting of andranes, cholestanes, cholic acids, corticosteroids, estraenes and pregnanes.

11. The agent delivery device of Claim 1, wherein said first pharmacological agent comprises an anti-inflammatory.

12. The agent delivery device of Claim 1, wherein said first pharmacological agent comprises an extracellular matrix (ECM) composition, said ECM composition including an ECM material selected from the group consisting of small intestine submucosa (SIS), urinary

bladder submucosa (UBS), urinary basement membrane (UBM), liver basement membrane (LBM), stomach submucosa (SS), mesothelial tissue, subcutaneous extracellular matrix, large intestine extracellular matrix, placental extracellular matrix, ornamentum extracellular matrix, heart extracellular matrix and lung extracellular matrix.

13. The agent delivery device of Claim 12, wherein said ECM composition includes at least one supplemental biologically active agent.

14. The agent delivery device of Claim 13, 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-α (TGF-α), transforming growth factor-β (TGF-β), 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-α (TNA-α), and placental growth factor (PLGF).

15. The agent delivery device of Claim 13, wherein said biologically active agent comprises a cell selected from the group consisting of a human embryonic stem cell, fetal cardiomyocyte, myofibroblast, mesenchymal stem cell, autotransplanted expanded cardiomyocytes, adipocyte, totipotent cell, pluripotent cell, blood stem cell, myoblast, adult stem cell, bone marrow cell, mesenchymal cell, embryonic stem cell, parenchymal cell, epithelial cell, endothelial cell, mesothelial cell, fibroblast, osteoblast, chondrocyte, exogenous cell, endogenous cell, hematopoietic stem cell, bone-marrow derived progenitor cell, myocardial cell, skeletal cell, fetal cell, undifferentiated cell, multi-potent progenitor cell, unipotent progenitor cell, monocyte, cardiac myoblast, skeletal myoblast, macrophage, capillary endothelial cell, xenogenic cell, allogenic cell and post-natal stem cell.

16. The agent delivery device of Claim 13, wherein said biologically active agent comprises a statin selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin.

17. The agent delivery device of Claim 13, wherein said biologically active agent comprises chitosan.

18. A method of treating a cardiovascular disorder, comprising:

providing a first pharmacological agent that is effective in treating the cardiovascular disorder;

providing an agent delivery device, said agent delivery device including a tissue access line that is configured to receive said first pharmacological agent therein and at least a first agent delivery line having a wall and a central lumen therethrough, said first agent delivery line being in fluid communication with said tissue access line, said first agent delivery line further including a plurality of dispersal lumens extending through said delivery line wall and in fluid communication with said central lumen, wherein, when said first agent delivery line is disposed in first cardiovascular tissue and said first pharmacological agent is introduced into said tissue access line, said plurality of dispersal lumens allow said first pharmacological agent to be transferred from said central lumen to said first cardiovascular tissue;

disposing said agent delivery device in said first cardiovascular tissue;

introducing said first pharmacological agent into said tissue access line, wherein said first pharmacological agent is delivered to said first cardiovascular tissue.

19. The method of Claim 18, wherein said agent delivery device includes a plurality of said first agent delivery lines.

20. The method of Claim 18, wherein said first pharmacological agent is selected from the group consisting of antibiotics or antifungal agents, anti-viral agents, anti-pain agents, anesthetics, analgesics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, anti-neoplastics, anti-spasmodics, modulators of cell-extracellular matrix interactions, proteins, hormones, growth factors, matrix metalloproteinases (MMPS), enzymes and enzyme inhibitors, anticoagulants and/or antithrombic agents, DNA, RNA, modified DNA and RNA, NSAIDs, inhibitors of DNA, RNA or protein synthesis, polypeptides, oligonucleotides, polynucleotides, nucleoproteins, compounds modulating cell migration, compounds modulating proliferation and growth of tissue, and vasodilating agents.

21. The method of Claim 18, wherein said first pharmacological agent comprises an anti-arrhythmic agent selected from the group consisting of Class I, II, III and IV anti-arrhythmic agents.

22. The method of Claim 18, wherein said first pharmacological agent comprises a statin selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin.

23. The method of Claim 18, wherein said first pharmacological agent comprises a growth factor selected from the group consisting of platelet derived growth factor (PDGF), epidermal growth factor (EGF), transforming growth factor-α (TGF-α), transforming growth factor-β (TGF-β), 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), platlet derived growth factor (PDGF), tumor necrosis factor-α (TNA-α), and placental growth factor (PLGF).

24. The method of Claim 18, wherein said first pharmacological agent comprises an extracellular matrix (ECM) composition, said ECM composition including an ECM material selected from the group consisting of small intestine submucosa (SIS), urinary bladder submucosa (UBS), urinary basement membrane (UBM), liver basement membrane (LBM), stomach submucosa (SS), mesothelial tissue, subcutaneous extracellular matrix, large intestine extracellular matrix, placental extracellular matrix, ornamentum extracellular matrix, heart extracellular matrix and lung extracellular matrix.

25. The method of Claim 24, wherein said ECM composition further includes a growth factor selected from the group consisting of a platelet derived growth factor (PDGF), epidermal growth factor (EGF), transforming growth factor-α (TGF-α), transforming growth factor-β (TGF-β), 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-α (TNA-α), and placental growth factor (PLGF).

26. The method of Claim 24, wherein said ECM composition further includes a statin selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin.

27. A method of treating damaged myocardial tissue in a cardiovascular structure, comprising:

providing a first pharmacological agent that is effective in treating the damaged myocardial tissue;

providing an agent delivery device, said agent delivery device including a myocardial tissue access line that is configured to receive said first pharmacological agent therein, and at least a first agent delivery line having a wall and a central lumen therethrough, said first agent delivery line being in fluid communication with said tissue access line, said agent delivery line being capable of transitioning from a pre-deployment configuration prior to being placed in first myocardial tissue to a post-deployment configuration when said agent delivery line is placed in said first myocardial tissue, said agent delivery line being formed in a post-deployment configuration, said post-deployment configuration conforming to a shape of said cardiovascular structure,

said first agent delivery line further including a plurality of dispersal lumens extending through said delivery line wall and in fluid communication with said central lumen, wherein, when said first agent delivery line is disposed in said first myocardial tissue and said first pharmacological agent is introduced into said tissue access line, said plurality of dispersal lumens allow said first pharmacological agent to be transferred from said central lumen to said first myocardial tissue;

forming said first agent delivery line in said pre-deployment configuration;

disposing said agent delivery device in said first myocardial tissue, wherein said agent delivery line is disposed proximate said damaged myocardial tissue, and wherein said agent delivery line transitions from said pre-deployment configuration to said post-deployment configuration, whereby said agent delivery line reinforces said cardiovascular structure; and

introducing said first pharmacological agent into said tissue access line, wherein said first pharmacological agent is delivered proximate said damaged myocardial tissue.

28. The method of Claim 27, wherein said agent delivery line comprises Nitinol®.

29. The method of Claim 27, wherein said agent delivery device includes a plurality of said first agent delivery lines.

30. The method of Claim 27, wherein said first pharmacological agent is selected from the group consisting of antibiotics or antifungal agents, anti-viral agents, anti-pain agents, anesthetics, analgesics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, anti-neoplastics, anti-spasmodics, modulators of cell-extracellular matrix interactions, proteins, hormones, growth factors, matrix metalloproteinases (MMPS), enzymes and enzyme inhibitors, anticoagulants and/or antithrombic agents, DNA, RNA, modified DNA and RNA, NSAIDs, inhibitors of DNA, RNA or protein synthesis, polypeptides, oligonucleotides, polynucleotides, nucleoproteins, compounds modulating cell migration, compounds modulating proliferation and growth of tissue, and vasodilating agents.

31. The method of Claim 27, wherein said first pharmacological agent comprises an anti-arrhythmic agent selected from the group consisting of Class I, II, III and IV anti-arrhythmic agents.

32. The method of Claim 27, wherein said first pharmacological agent comprises a statin selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin.

33. The method of Claim 27, wherein said first pharmacological agent comprises a growth factor selected from the group consisting of platelet derived growth factor (PDGF), epidermal growth factor (EGF), transforming growth factor-α (TGF-α), transforming growth factor-β (TGF-β), 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), platlet derived growth factor (PDGF), tumor necrosis factor-α (TNA-α), and placental growth factor (PLGF).

34. The method of Claim 27, wherein said first pharmacological agent comprises an extracellular matrix (ECM) composition, said ECM composition including an ECM material selected from the group consisting of small intestine submucosa (SIS), urinary bladder submucosa (UBS), urinary basement membrane (UBM), liver basement membrane (LBM), stomach submucosa (SS), mesothelial tissue, subcutaneous extracellular matrix, large intestine extracellular matrix, placental extracellular matrix, ornamentum extracellular matrix, heart extracellular matrix and lung extracellular matrix.

35. The method of Claim 34, wherein said ECM composition further includes a growth factor selected from the group consisting of a platelet derived growth factor (PDGF), epidermal growth factor (EGF), transforming growth factor-α (TGF-α), transforming growth factor-β (TGF-β), 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-α (TNA-α), and placental growth factor (PLGF).

36. The method of Claim 34, wherein said ECM composition further includes a statin selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin.

CLAIMS

1. An intra-myocardial agent delivery device, comprising:

a myocardial tissue access line that is configured to receive a pharmacological agent therein and provide direct fluid access of said pharmacological agent to damaged myocardial tissue of a cardiovascular structure, and an agent delivery line comprising a wall and a central lumen therethrough, said agent delivery line being in fluid communication with said tissue access line, said agent delivery line comprising Nitinol®, said agent delivery line being capable of transitioning from a pre-deployment configuration prior to being placed proximate said damaged myocardial tissue to a post-deployment configuration when said agent delivery line is placed proximate said damaged myocardial tissue, said post-deployment configuration conforming to a shape of said cardiovascular structure,

said agent delivery line further comprising a plurality of dispersal lumens extending through said delivery line wall and in fluid communication with said central lumen, wherein, when said agent delivery line is disposed proximate said damaged myocardial tissue and said pharmacological agent is introduced into said tissue access line, said plurality of dispersal lumens allow said pharmacological agent to be transferred from said central lumen to said damaged myocardial tissue.

2. The agent delivery device of Claim 1, wherein said device includes a plurality of said agent delivery lines.

3. The agent delivery device of Claim 1, wherein said device includes an external pump, said pump being in fluid communication with said tissue access line and configured to introduce said pharmacological agent into said tissue access line with a first fluid pressure.

4. The agent delivery device of Claim 1, wherein said first pharmacological agent is selected from the group consisting of antibiotics or antifungal agents, anti-viral agents, anti-pain agents, anesthetics, analgesics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, anti-neoplastics, anti-spasmodics, modulators of cell-extracellular matrix interactions, proteins, hormones, growth factors, matrix metalloproteinases (MMPS), enzymes and enzyme inhibitors, anticoagulants and/or antithrombotic agents, DNA, RNA, modified DNA and RNA, NSAIDs, inhibitors of DNA, RNA or protein synthesis,

polypeptides, oligonucleotides, polynucleotides, nucleoproteins, compounds modulating cell migration, compounds modulating proliferation and growth of tissue, and vasodilating agents.

5. The agent delivery device of Claim 1, wherein said pharmacological agent is selected from the group consisting of antihypertensive agents, inotropic agents, antiatherogenic agents, beta-blockers, sympathomimetic agents, phosphodiesterase inhibitors, diuretics, vasodilators, thrombolytic agents, cardiac glycosides, and antineoplastic agents.

6. The agent delivery device of Claim 1, wherein said pharmacological agent comprises an anti-arrhythmic agent selected from the group consisting of Class I, II, III and IV anti-arrhythmic agents.

7. The agent delivery device of Claim 1, 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 agent delivery device of Claim 1, wherein said pharmacological agent comprises an antibiotic selected from the group consisting of aminoglycosides, cephalosporins, chloramphenicol, clindamycin, erythromycins, fluoroquinolones, macrolides, azolides, metronidazole, penicillins, tetracyclines, trimethoprim-sulfamethoxazole and vancomycin.

9. The agent delivery device of Claim 1, wherein said pharmacological agent comprises a growth factor selected from the group consisting of platelet derived growth factor (PDGF), epidermal growth factor (EGF), transforming growth factor-α (TGF-α), transforming growth factor-β (TGF-β), fibroblast growth factor – 2 (FGF-2), vascular epithelial growth factor (VEGF), hepatocyte growth factor (HGF), insulin-like growth factor (IGF), nerve growth factor (NGF), tumor necrosis factor-α (TNA-α), and placental growth factor (PLGF).

10. The agent delivery device of Claim 1, wherein said pharmacological agent comprises a steroid selected from the group consisting of andranes, cholestanes, cholic acids, corticosteroids, estraenes and pregnanes.

11. The agent delivery device of Claim 1, wherein said pharmacological agent comprises an anti-inflammatory.

12. The agent delivery device of Claim 1, wherein said pharmacological agent comprises an extracellular matrix (ECM) composition, said ECM composition including an ECM material selected from the group consisting of small intestine submucosa (SIS), urinary bladder submucosa (UBS), urinary basement membrane (UBM), liver basement membrane (LBM), stomach submucosa (SS), mesothelial tissue, subcutaneous extracellular matrix, large intestine extracellular matrix, placental extracellular matrix, omentum extracellular matrix, heart extracellular matrix and lung extracellular matrix.

13. The agent delivery device of Claim 12, wherein said ECM composition includes at least one supplemental biologically active agent.

14. The agent delivery device of Claim 13, 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-α (TGF-α), transforming growth factor-β (TGF-β), fibroblast growth factor-2 (FGF-2), vascular epithelial growth factor (VEGF), hepatocyte growth factor (HGF), insulin-like growth factor (IGF), nerve growth factor (NGF), tumor necrosis factor-α (TNA-α), and placental growth factor (PLGF).

15. The agent delivery device of Claim 13, wherein said biologically active agent comprises a cell selected from the group consisting of a human embryonic stem cell, fetal cardiomyocyte, myofibroblast, mesenchymal stem cell, autotransplanted expanded cardiomyocytes, adipocyte, totipotent cell, pluripotent cell, blood stem cell, myoblast, adult stem cell, bone marrow cell, mesenchymal cell, embryonic stem cell, parenchymal cell, epithelial cell, endothelial cell, mesothelial cell, fibroblast, osteoblast, chondrocyte, exogenous cell, endogenous cell, hematopoietic stem cell, bone-marrow derived progenitor cell, myocardial cell, skeletal cell, fetal cell, undifferentiated cell, multi-potent progenitor cell, unipotent progenitor cell, monocyte, cardiac myoblast, skeletal myoblast, macrophage, capillary endothelial cell, xenogeneic cell, allogeneic cell and post-natal stem cell.

16. The agent delivery device of Claim 13, wherein said biologically active agent comprises a statin selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin.

17. The agent delivery device of Claim 13, wherein said biologically active agent comprises chitosan.