CLAIMS

What is claimed is:

1. A medical assembly for minimally invasively implanting an atrial sealing skirt in the heart at an atrial sealing skirt deployment site comprising:

an atrial sealing skirt configured for receiving a valve and for endovascular introduction and implantation at a deployment site and configured and sized to replace a native heart valve, said atrial sealing skirt having a portion being configured to substantially conform to an atrial floor adjacent the valve deployment site;

an anchor assembly configured and sized for endovascular introduction for implanting the anchor to an intracardiac wall at an implantation site and comprising a delivery cable;

a tether including at least one cord connected to said anchor and said atrial sealing skirt for operatively connecting said atrial sealing skirt and said anchor;

a removable anchor delivery system for introducing said anchor endovascularly; and

a removable atrial sealing skirt delivery system for positioning and sealing the atrial sealing skirt.

2. The medical assembly according to Claim 1 wherein said anchor assembly comprises:

an anchor cap having a proximal and distal end;

an anchor screw extending from the anchor cap distal end and configured for penetration a predetermined distance into the intracardiac wall at the implantation site; and

at least one lock on said anchor cap for locking said tether, said lock being selectively moved from a first locked position to a second unlocked position.

3. The medical assembly according to Claim 2 wherein said at least one lock is a locking arm extending radially outwardly from said anchor cap.

4. The medical assembly according to Claim 2 wherein said anchor comprises at least two of said locks.

5. The medical assembly according to Claim 1 comprising:

an anchor cap having a proximal and distal end wherein said proximal end includes a first surface configuration;

an anchor screw extending from the anchor cap distal end and configured for penetration a predetermined distance into the intracardiac wall at the implantation site; and

said delivery cable comprises a distal end having a second surface configuration configured to mate with said anchor cap proximal end surface configuration.

6. The medical assembly according to Claim 5 wherein said delivery cable comprises a flexible wire.

7. The medical assembly according to Claim 5 wherein said anchor cap first surface configuration is defined by a cavity having threaded sidewalls and said second configuration of said delivery cable distal end is an outer surface configuration which is threaded to mate and engage said anchor cap wherein said anchor delivery cap rotates said anchor cap when rotational forces are applied thereto.

8. The medical assembly according to Claim 6 wherein said tether comprises:

a docking ring defining a central aperture for receiving the flexible wire of the delivery cable; and

at least one tether rod moveably connected to said docking ring.

9. The medical assembly according to Claim 8 wherein said anchor cap comprises at least one lock, said lock being selectively moved from a first locked position to a second unlocked position and said tether and said docking ring cooperates with said at least one lock of the anchor cap for securing the tether on the anchor cap when said lock is in said first position.

10. The medical assembly according to Claim 9 wherein said at least one tether rod is rotatably connected to said docking ring and is substantially rigid.

11. The medical assembly according to Claim 10 wherein a distal end of said tether rod defines a hook and said docking ring includes an eyelet configured for receipt of said hook.

12. The medical assembly according to Claim 8 wherein said tether further includes at least one suture extending from a proximal end of said at least tether rod.

13. The medical assembly according to Claim 12 wherein said tether comprises at last two of said tether rods and at least two of said sutures wherein each of said at least two of said sutures extends from a respective one of said at least two of said tether rods.

14. The medical assembly according to Claim 2 wherein said anchor delivery assembly comprises:

an anchor delivery guide defining a longitudinally extending lumen and having a proximal and distal end;

an anchor delivery rod defining a longitudinally extending lumen and having a proximal and distal end and having a distal portion wherein side walls of said delivery rod lumen have a second configuration and wherein a proximal portion of said anchor cap includes a first configuration for cooperating with said delivery rod lumen second configuration for selectively mating therewith for implantation of said anchor screw at the implantation site.

15. The medical assembly according to Claim 14 wherein said anchor delivery assembly further comprises a sheath defining a longitudinally extending lumen for receiving a portion of said anchor delivery guide, said sheath having a length less than the length of the said anchor delivery guide defined between said proximal and distal ends.

16. The medical assembly according to Claim 14 further comprising a guide handle for receiving a proximal portion of said anchor delivery guide.

17. The medical assembly according to Claim 1 further comprising a J-wire configured for endovascular insertion to guide said anchor delivery system.

18. The medical assembly according to Claim 14 wherein said atrial anchor delivery system further comprises a rotating handle on a proximal end of said delivery rod for facilitating rotation of said delivery rod to rotate said anchor.

19. The medical assembly according to Claim 1, said tether further comprising at least one suture extending from a proximal end of said at least one cord.

20. The medical assembly according to Claim 1 further comprising a tether delivery assembly comprising a removeable tether delivery sheath defining a longitudinally extending lumen configured for receipt of said tether.

21. The medical assembly according to Claim 1 wherein said atrial skirt delivery system comprises:

an atrial sealing skirt delivery guide having proximal and distal ends and defining an inner guide extending lumen therebetween wherein a delivery sheath is removable and positioned along said delivery cable and wherein said sheath includes said atrial sealing skirt operatively connected to said cord which extends within said sheath lumen.

22. The medical assembly according to Claim 21 wherein said tether comprises a docking ring defining a central aperture for receiving the flexible wire of the delivery cable and at least one tether rod moveably connected to said docking ring and said delivery guide also includes said tether within said lumen wherein said atrial sealing skirt is connected to said tether within said lumen.

23. The medical assembly according to Claim 22 wherein said atrial skirt delivery system further comprises an atrial sealing skirt deployment knob having a central channel for receiving a proximal portion of said atrial sealing skirt delivery guide and wherein said atrial sealing skirt delivery guide is retractable within said atrial sealing skirt deployment knob when retracted.

24. The medical assembly according to Claim 23 wherein said atrial skirt delivery system further comprises at least one positioning rod having a central lumen for being inserted over said at least one cord of said tether and wherein said at least one positioning rod has a length sufficient to extend proximal to said deployment knob and into the heart so as to contact said atrial sealing skirt.

25. The medical assembly according to Claim 1 further comprising a locking system for locking said atrial sealing skirt positioned on the atrial floor and wherein said atrial skirt delivery system further comprises at least one positioning rod having a central lumen for being inserted over said at least one cord of said tether, said atrial sealing skirt comprising an atrial top brim, and said locking system comprises at least one conduit extending below said top brim and wherein said top brim defines at least one aperture of said conduit and said locking system further comprises a detachable lock positioned within said conduit configured to cooperate with said at least one positioning rod to lock said top brim on the atrial floor.

26. The medical assembly according to Claim 25 wherein said detachable lock defines a central lumen and said cord of said tether is received within said lock lumen.

27. The medical assembly according to Claim 26 wherein said locking system further comprises a first gateway hypotube defining a central lumen and configured for receipt by said detachable lock lumen and configured to cooperate with said detachable lock to secure said at least one cord.

28. The medical assembly according to Claim 1 wherein said atrial sealing skirt defines a valve receptacle and said medical assembly comprises a valve within said valve receptacle.

29. An atrial sealing skirt configured for receiving a valve and for endovascular introduction and implantation at a deployment site and configured and sized to replace a native heart valve, said atrial sealing skirt being configured to substantially conform to an atrial floor adjacent the atrial sealing skirt deployment site and comprising:

an atrial skirt body which is generally cylindrical and which defines a valve receptacle;

an atrial skirt top brim extending circumferentially around an upper edge of said atrial skirt body, and wherein said atrial sealing skirt is compressible when constrained and expands when released from constraints;

at least one conduit having an open upper end defined by an aperture in said skirt brim wherein said conduit extends from said aperture and below said skirt brim;

at least one extension member for supporting said skirt brim, said extension member having a base end adjacent said skirt body upper edge which extends outwardly substantially to an outer edge of said skirt brim;

at least one body support for supporting said skirt body; and

a membrane covering said at least one extension member and said at least one body support for forming the skirt brim and body.

30. The atrial sealing skirt according to Claim 29 wherein said atrial sealing skirt defines a valve receptacle and said medical assembly comprises a valve within said valve receptacle.

31. The atrial sealing skirt according to Claim 29, wherein the open upper end is positioned below said atrial skirt top brim wherein said conduit extends distally below said atrial skirt top brim adjacent a side surface of said atrial skirt body.

32. The atrial sealing skirt according to Claim 31, further comprising a valve within said valve receptacle

33. The atrial sealing skirt according to Claim 29, 31 or 32 wherein said at least one extension member is non-linear.

34. The atrial sealing skirt according to Claim 29, 31 or 32 wherein said at least one extension member is a plurality of said extension members.

35. The atrial sealing skirt according to Claim 29, 31 or 32 wherein said at least one body support is a plurality of extension members forming a lattice-like structure.

36. The atrial sealing skirt according to Claim 29, 31 or 32 wherein said at least one conduit is at least two conduits.

37. The atrial sealing skirt according to Claim 29, 31 or 32 wherein said at least one conduit extends adjacent an outer side surface of said atrial skirt body.

38. The atrial sealing skirt according to Claim 29, 31 or 32 wherein said membrane is formed of a synthetic material.

39. The atrial sealing skirt according to Claim 29 wherein said at least one conduit is configured for receipt of a locking system for locking said atrial sealing skirt positioned on the atrial floor.

40. The atrial sealing skirt according to Claim 39 wherein said locking system comprises a detachable lock positioned within said conduit to lock said top brim against the atrial floor.

41. The atrial sealing skirt according to Claim 40 wherein said detachable lock defines a central lumen configured for receipt of a tether for securing said atrial sealing skirt.

42. The atrial sealing skirt according to Claim 41 wherein said locking system further comprises a first hypotube defining a central lumen and configured for receipt by said detachable lock lumen and configured to cooperate with said detachable lock.

43. The atrial sealing skirt according to Claim 41 wherein said locking system further comprises a second hypotube defining a central lumen and configured for receipt by said first hypotube.

44. The atrial sealing skirt according to Claim 29, 31 or 32 wherein said atrial skirt top brim is generally concave prior to conformance with the atrial floor.

45. The medical assembly according to Claim 2 wherein said anchor screw predetermined distance is a distance sufficient to penetrate and exit an intracardiac wall at said implantation site.

46. The medical assembly according to Claim 45 wherein said anchor assembly comprises:

an anchor shaft having a distal end for penetrating the intracardiac wall and a distal portion and extending from the anchor cap distal end and said anchor screw extends circumferentially around said anchor shaft;

said distal portion of said anchor shaft defines at least two anchor sectors including a respective portion of said anchor screw; and

tensioning means operatively connected to said anchor sectors wherein said tensioning means is released when said anchor sectors have penetrated and exited the intracardiac wall so as to expand and anchor said anchor assembly.

47. The medical assembly according to Claim 46 wherein said tensioning means is a tensioning line extending through said anchor shaft and said line includes at least two distal lines for connecting to a respective one of said at least two anchor sectors.

48. The medical assembly according to Claim 2 wherein said anchor comprises:

an anchor shaft defining a first surface configuration and said anchor screw extends distally from said anchor shaft;

wherein said at least one lock extends from said anchor shaft between a first locked and a second unlocked position;

a removable anchor connector and a connector rod connected to said anchor connector, said anchor connector having a second surface configuration wherein said second surface configuration and said anchor shaft first surface configuration are mating surfaces wherein said anchor connector maintains the at least one lock in said second unlocked position when mated with said anchor shaft; and

said tether comprises a tether ring configured for receipt of said anchor connector and anchor rod and for cooperating with said at least one lock when said anchor connector is removed so as to be locked in position on said anchor shaft, said tether ring defining coupling means.

49. The medical assembly according to Claim 48 wherein said anchor shaft first surface configuration includes at least one flange and recess and said anchor connector second surface configuration includes at least one mating recess and flange for coupling with said anchor shaft.

50. The atrial sealing skirt according to Claim 31 or 32, further comprising a lock positioned within said conduit to lock said atrial skirt top brim against the atrial floor wherein said lock is configured to be unlocked to permit repositioning of said atrial skirt.

51. The atrial sealing skirt according to Claim 50, wherein said lock defines a central lumen configured for receipt of a tether for securing said atrial sealing skirt.

52. The atrial sealing skirt according to Claim 51, further comprising a first hypotube defining a central lumen and configured for receipt by said lock lumen and configured to cooperate with said lock.

53. The atrial sealing skirt according to Claim 52, further comprising a second hypotube defining a central lumen and configured for receipt by said first hypotube.

54. The atrial sealing skirt according to Claim 52, wherein said lock defines first cooperating surface and said first hypotube defines a second cooperating surface wherein said first and second mating surfaces cooperate to selectively retain said first hypotube within said detachable lock.

55. The atrial sealing skirt according to Claim 50, wherein said lock has a first proximal end defining a threaded aperture and a distal end with a central cavity extending between said ends.

56. The atrial sealing skirt according to Claim 50, wherein said lock further comprises a clamp within said central cavity wherein said claim is moveable between a first locked and second unlocked position to selectively lock said cord.

57. The atrial sealing skirt according to Claim 55, wherein said lock further comprises:

a sidewall defining lock central cavity and defining an exit portion on said sidewall; and

an atrial anchor within said lock central cavity, said anchor having a first end extending inwardly from said sidewall and a second end wherein said anchor is moveable between a first locked position wherein said anchor extends through said exit port in said first locked position to selectively lock said cord.

58. The atrial sealing skirt according to Claim 57, wherein said lock includes at least two of said atrial anchors, said lock sidewall defining at least two exit ports configured for receipt of said atrial anchors wherein forces applied to said atrial anchors extend said atrial anchors outwardly from said lock central cavity through said exit ports.

59. The atrial sealing skirt according to Claim 50, wherein said conduit comprises a sidewall and said lock is removable from said sidewall.

60. The atrial sealing skirt according to Claim 31 or 32, wherein said conduit has a proximal portion adjacent said atrial skirt top brim and a distal portion extending below said atrial skirt top brim wherein said distal portion is at least equal to said proximal portion in length.

61. The atrial sealing skirt according to Claim 60, wherein said distal portion extending below said atrial skirt top brim wherein said distal portion is greater than said proximal portion in length.

62. The atrial sealing skirt according to Claim 31 or 32, wherein said conduit is supported by said skirt body.

63. The atrial sealing skirt according to Claim 62, wherein said conduit extends parallel to and alongside said side surface of said skirt body.

64. The atrial sealing skirt according to Claim 62, wherein said side surface of said skirt body is an exterior surface.

65. The atrial sealing skirt according to Claim 31 or 32, wherein said conduit comprises a solid sidewall.

66. The atrial sealing skirt according to Claim 31 or 32, wherein said membrane is formed of a biologic material.

67. The atrial sealing skirt according to Claim 31 or 32, wherein said skirt top brim includes an aperture and said aperture defines said open upper end of said conduit.