

CLAIMS

1. An access device (1) for a heart chamber including a permanently implantable apical base plate (100) and a sealing unit (3), which is not included in a hemostatic valve, and being configured to provide a separation of a wet zone in a heart chamber from a dry zone with a gaseous environment inside a patient body at the same time.
2. The access device of claim 1, including said apical base plate (100) having a tubular through port (120) adapted to be arranged across cardiac tissue, said access device (1) having a first, open patient configuration wherein a removable hemostatic valve unit (2) is removably attached to a proximal side of said apical base plate (100), and having a second, closed patient configuration wherein said sealing unit (3), that optionally includes a feed-through port (320), is preferably distally attached to said base plate (100) for providing said separation of zones.
3. The access device of claim 2, wherein said sealing unit (3) is deliverable through said hemostatic valve (2) for attachment to said apical base plate (100); and wherein said second configuration is alternative to said first configuration; or wherein said second configuration is in addition to said first configuration during transition to said second configuration only.
4. The access device of claim 2 or 3, wherein said sealing unit (3) is configured to be delivered through said hemostatic valve unit (2) for said transition from said first configuration to said second configuration.
5. The access device of any of claims 1 to 4, wherein said apical base (100) plate includes a flange unit (160) for sealingly attaching said base plate (100) to a heart having said heart chamber.
6. The access device of claim 5, wherein said flange unit (160) is attachable to an outside of said cardiac tissue by attachment elements, said attachment elements preferably being sutures (165), hooks, clips, staples, and/or screws.
7. The access device of claim 5 or 6, wherein said flange unit (160) including eyelets for receiving sutures (165) for attachment of said flange unit (160) to said heart.
8. The access device of any of claims 2 to 7, wherein said removable hemostatic valve (2) is connectable to said through port (120), preferably at a proximal side of said apical base plate (100).
9. The access device of any of claims 2 to 8, wherein said removable hemostatic valve (2) is a balloon valve with controllable balloon pressure.
10. The access device of any of claims 2 to 9, wherein said removable hemostatic valve (2) has a longitudinally splittable housing (200) of at least two releasably attachable housing parts.
11. The access device of any of claims 2 to 10, wherein said removable hemostatic valve (2) has a through port (225) in said first configuration providing a communication channel for delivery of a medical device, to and from the interior (15) of said heart, and for delivery of said sealing unit (3) for said transition to said second configuration or subsequent replacement of said sealing unit (3).
12. The access device of any of claims 1 to 11, comprising a drive unit (6) connected to said base plate (100) in said second configuration wherein said hemostatic valve (2) is configured to be removed from said apical base plate (100) when said drive unit (6) is connected to said apical base plate (100).
13. The access device of any of claims 2 to 12, wherein said sealing unit (3) includes at least one membrane, such as a bellow (310) and preferably a first sealing member (325) arranged for sealing against said tubular through port (120).
14. The access device of claim 13, including said bellow attached to said apical base plate to extend distally from said apical base plate.

15. The access device of claim 13 or 14, including multiple membranes or bellows in a membrane in membrane or bellow in bellow arrangement.
16. The access device of claim 15, wherein said different bellows, in a bellow in bellow solution, include different materials with different material properties.
- 5 17. The access device of claim 13 or 14, wherein different bellows are made of a same material.
18. The access device of any of claims 13 to 17, wherein said at least one membrane or bellow is made of an elastic material.
19. The access device of any of claims 2 to 18, wherein said sealing unit (3) includes said feed-through port (320), and optionally a second sealing member (326) at said feed-through port (320).
- 10 20. The access device of any of claims 1 to 19, wherein said sealing unit (3) including a detaining unit (330) to provide a detainment of blood and/or gas.
21. The access device of any of claims 1 to 20, including a cardiac assist unit having a driving rod (610) arranged to pass transapically through said sealing unit (3) into said heart.
- 15 22. A removable and/or re-attachable hemostatic valve unit (2) having a longitudinally splittable housing (200) with a distal end and a proximal end connectable at said distal end to an apical base plate (100) of an access device (1) for a heart, such as of any of claims 1 to 21, including a pneumatic valve in a through port (225) of said valve unit (2) between said distal end and said proximal end.
23. The hemostatic valve unit of claim 22, wherein said pneumatic valve includes an inflatable
- 20 balloon member or a tube coil, for controlling an inner passage in said through port (225) of said hemostatic valve unit (2).
24. The hemostatic valve unit of claim 22 or 23, including said housing (200) having a proximal end with an opening to said through port (225) of said valve unit (2) for receiving a medical device to be passed through said through port (225).
- 25 25. The hemostatic valve unit of any of claims 22 to 24, wherein said housing (200) being longitudinally splittable for removal of said valve unit in a radial direction from said apical base plate (100) and for optional reattachment to said apical base plate (100).
26. The hemostatic valve unit of any of claims 22 to 25, including a reservoir unit for maintaining a substantially constant pressure on said pneumatic valve.
- 30 27. A medical system including a cardiac assist unit configured to be transapically implanted, wherein said cardiac assist unit is attachable to a sealed access device (1), preferably said access device (1) of any of claims 1 to 21.
- 35 28. A sealed access device (1), preferably said access device (1) of any of claims 1 to 21, including a connection interface (110) configured to matingly engage with multiple medical devices having mating connection interfaces, respectively.
29. The sealed access device (1) of claim 28, wherein said connection interface (110) is on a proximal side of said access device (1), and said access device (1) is sealed on a distal side, opposite said
- 40 proximal side.
30. The sealed access device (1) of claim 28 or 29, wherein said connection interface (110) includes a freely rotatable connection of said medical device relative said access device (1), wherein said freely rotatable connection optionally includes a three-dimensional movement around a pivot point of said connection interface (110).
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31. A system for accessing a heart of a patient comprising:
 an apical base plate for permanent placement at an apex region of said heart and providing access
 to a heart chamber of said heart;
 a sealing unit matable with said apical base plate;
 5 said heart chamber defining a wet zone;
 a dry zone created from mating said sealing unit to said apical base unit,
 said dry zone separated from said wet zone;
 said dry zone being constituted by a gaseous environment; and,
 said dry zone being disposed inside said patient during use of said system.
- 1 0 32. A system according to claim 31, further comprising:
 a hemostatic valve matable with said apical base plate.
33. A system according to claim 32, further comprising:
 a first configuration wherein only said hemostatic valve is mated with said apical base;
 a second configuration wherein only said sealing unit is mated with said apical base; and,
 1 5 a third configuration where both said hemostatic valve and said sealing unit are mated to said
 apical base.
34. A system according to claim 33, wherein said third configuration is constituted by said sealing
 unit being placed inside said hemostatic valve.
35. A system according to claim 31, further comprising a flange unit attached to said apical base
 2 0 plate and attachable to said heart.
36. A system according to claim 35, wherein said flange unit includes tissue attachment elements.
37. A system according to claim 36, wherein said tissue attachment elements comprise eyelets for
 receiving suture material.
38. A system according to claim 32, wherein said apical base plate includes a through-port and
 2 5 wherein said hemostatic valve is matable with said apical base plate to said through-port.
39. A system according to claim 32, wherein said hemostatic valve comprises a balloon valve
 having a balloon and a mechanism to control balloon pressure.
40. A system according to claim 32, wherein said hemostatic valve comprises a longitudinally
 splittable housing.
- 3 0 41. A system according to claim 32, wherein said hemostatic valve comprises a through-port
 communication channel extending from a proximal end of said hemostatic valve to an interior of said heart.
42. A system according to any of claims 31 to 41, further comprising a drive unit matable to said
 apical base plate.
43. A system according to claim 31, wherein said sealing unit includes a bellows section and a
 3 5 first sealing member, said first sealing member sized to sealingly mate with a through-port of said apical base.
44. A system according to claim 31, wherein said sealing unit includes a feed-through port.
45. A system according to any of claims 31 to 44, further comprising a cardiac assist unit.
46. A system according to claim 45, wherein said cardiac assist unit comprises a drive rod sized
 to pass transapically through said sealing unit.
- 4 0 47. A system according to any of claims 31 to 46, further comprising a plug insertable into said
 apical base plate so as to close said apical base plate.
48. A system according to claim 45 or 46, wherein said cardiac assist unit is detachably
 connected to said apical base plate.

49. A system according to any of claims 31 to 48, further comprising a connection interface associated with said apical base plate; said connection interface configured to engage multiple medical devices.

50. A system according to claim 49, wherein said connection interface is disposed on a proximal side of said system and wherein said system further includes a seal disposed on a distal side of said system.

51. A system according to claim 49 or 50, wherein said connection interface comprises a connection portion that is rotatable relative to said apical base plate.

52. A device for providing access to a heart of a patient comprising:
a base plate sized for attachment to said heart;
said base plate sized to extend from an exterior of said heart to an internal chamber of said heart;
a sealing unit connectable to said base plate so as to create a barrier between said internal chamber of said heart and an external environment; and,
said external environment being inside said patient.