

CLAIMS

What is claimed is:

1. A valve repair device for repairing a native valve of a patient, the valve repair device comprising:

a coaption element having an opening;

an expandable coaption portion disposed within the coaption element and configured to expand outward through the opening in the coaption element, the expandable coaption portion extending between a proximal end and a distal end;

an actuation member that engages the expandable coaption portion to expand and retract the expandable coaption portion; and

an anchor portion having at least one anchor configured to attach to the native valve of the patient.

2. The valve repair device of claim 1, wherein the expandable coaption portion expands symmetrically through two openings in the coaption element.

3. The valve repair device of claim 1, wherein the expandable coaption portion expands asymmetrically through two openings in the coaption element such that the distal end of the expandable coaption portion extends to a greater width than the proximal end of the expandable coaption portion.

4. The valve repair device of claim 1, wherein the expandable coaption portion expands asymmetrically through two openings in the coaption element such that the proximal end of the expandable coaption portion extends to a greater width than the distal end of the expandable coaption portion.

5. The valve repair device of any one of claims 1, 3, or 4, wherein:

the expandable coaption portion comprises first and second expandable coaption portions;

the first expandable coaption portion extends through a first opening in the coaption element to a first distance; and

the second expandable coaption portion extends through a second opening in the coaption element to a second distance.

6. The valve repair device of any one of claims 1-5, wherein the actuation member pushes on one of the proximal end and the distal end of the expandable coaption portion to cause the expandable coaption portion to expand.

~~7. The valve repair device of any one of claims 1-5, wherein the actuation member pulls on one of the proximal end and the distal end of the expandable coaption portion to cause the expandable coaption portion to expand.~~

87. The valve repair device of any one of claims 1-5, wherein the actuation member pushes on one of the proximal end and the distal end of the expandable coaption portion and pulls on the other of the proximal end and the distal end of the expandable coaption portion to cause the expandable coaption portion to expand.

98. The valve repair device of any one of claims 1-87, wherein the actuation member is a flexible actuation member that is routed through the distal end to the proximal end of the expandable coaption portion.

109. The valve repair device of any one of claims 1-98, wherein the expandable coaption portion is attached to a proximal portion of the coaption element.

~~11. The valve repair device of any one of claims 1-9, wherein the expandable coaption portion is attached to a distal portion of the coaption element.~~

1210. The valve repair device of any one of claims 1-119, further comprising a biasing member extending between the proximal end and the distal end of the expandable coaption portion that biases the expandable coaption portion toward the extended condition.

1311. The valve repair device of any one of claims 1-119, further comprising a biasing member extending between the proximal end and the distal end of the expandable coaption portion that biases the expandable coaption portion toward the retracted condition.

~~14~~12. The valve repair device of any one of claims 1-~~13~~11, further comprising:

a locking member extending between the proximal end and the distal end of the expandable coaption portion; and

a lock that has a locked condition and an unlocked condition;

wherein in the unlocked condition, the lock allows the locking member to change length as the proximal and distal ends move together or apart; and

wherein in the locked condition, the lock prohibits the locking member to change length as the proximal and distal ends move together or apart.

~~15~~13. The valve repair device of any one of claims 1-~~14~~12, wherein the actuation member comprises a rotatable cam member that is rotatable between a first position and a second position to cause the expandable coaption portion to expand from a retracted condition to an extended condition.

~~16~~14. The valve repair device of any one of claims 1-~~15~~13, wherein the valve repair device comprises:

a shaft;

a collar that the shaft extends through, the collar being attached to the coaption element;

a cap attached to the shaft such that the cap can be moved by the shaft away from the collar; and

a plurality of paddle portions, wherein the paddle portions are moveable between an open position and a closed position and are configured to attach to the native valve of the patient;

wherein movement of the cap toward the collar causes the paddle portions to move to the closed position, and movement of the cap away from the collar causes the paddle portions to move to the open position.

~~17~~15. The valve repair device of claim ~~16~~14, wherein the shaft extends through expandable coaption portion.

~~1816.~~ The valve repair device of claim ~~1614~~ or ~~1715~~, wherein the expandable coaption portion expands towards the paddle portions of the valve repair device.

~~1917.~~ The valve repair device of any one of claims 1-~~1816~~, wherein a width of the expandable coaption portion is inversely proportional to a length of the expandable coaption portion.

~~2018.~~ The valve repair device of any one of claims 1-~~1917~~, wherein the expandable coaption portion is formed from a tube of braided material.

~~21.—The valve repair device of any one of claims 1-20, wherein the expandable coaption portion is formed from a shape memory alloy.~~

~~22.—The valve repair device of any one of claims 1-20, wherein the expandable coaption portion is formed from an elastomeric material.~~

~~23.—The valve repair device of any one of claims 1-22, further comprising a cover extending over one or more of the coaption element and expandable coaption portions.~~

~~24.—The valve repair device of any one of claims 1-24, wherein the coaption element is configured to close a gap in the native valve of the patient when the valve repair device is attached to the native valve.~~

~~25.—An expandable spacer assembly comprising:~~

~~a central shaft;~~

~~an actuation tube rotatably disposed around the central shaft;~~

~~an expandable spacer having a first end secured to the central shaft and a second end secured to the locking tube;~~

~~wherein rotation of the actuation tube relative to the central shaft causes the expandable spacer to expand.~~

~~26.—The expandable spacer assembly of claim 25, wherein a locking portion of the central shaft engages a locking portion of the expandable spacer to hold the spacer in a~~

~~retracted position, an expanded position, and a plurality of positions between the retracted position and the expanded position.~~

~~27. — The expandable spacer assembly of claim 25 or claim 26, wherein a teeth of the central shaft engage teeth of the expandable spacer to hold the spacer in a retracted position, an expanded position, and a plurality of positions between the retracted position and the expanded position.~~

~~28. — The expandable spacer assembly of any one of claims 25-27, wherein a proximal end of the spacer is fixed to a proximal end of the shaft and a distal end of the spacer is fixed to a distal end of the actuation tube.~~

~~29. — The expandable spacer assembly of any one of claims 25-28, wherein the spacer comprises a tube with a plurality of cuts.~~

~~30. — The expandable spacer assembly of any one of claims 25-29, wherein the spacer comprises a tube with a plurality of spiral shaped cuts.~~

~~31~~19. A system for repairing a native valve of a patient, the system comprising:

a delivery catheter;

a valve repair device coupled to the delivery catheter, wherein the valve repair device comprises:

a coaption element having an opening;

an expandable coaption portion disposed within the coaption element and configured to expand outward through the opening in the coaption element, the expandable coaption portion extending between a proximal end and a distal end;

an actuation member that engages the expandable coaption portion to expand and retract the expandable coaption portion; and

an anchor portion having at least one anchor configured to attach to the native valve of the patient.

3220. The system of claim 3119, wherein the expandable coaption portion expands symmetrically through two openings in the coaption element.

3321. The system of claim 3119, wherein the expandable coaption portion expands asymmetrically through two openings in the coaption element such that the distal end of the expandable coaption portion extends to a greater width than the proximal end of the expandable coaption portion.

3422. The system of claim 3119, wherein the expandable coaption portion expands asymmetrically through two openings in the coaption element such that the proximal end of the expandable coaption portion extends to a greater width than the distal end of the expandable coaption portion.

3523. The system of any one of claims 3119, 3321, or 3422, wherein:

the expandable coaption portion comprises first and second expandable coaption portions;

the first expandable coaption portion extends through a first opening in the coaption element to a first distance; and

the second expandable coaption portion extends through a second opening in the coaption element to a second distance.

3624. The system of any one of claims 3119-3523, wherein the actuation member pushes on one of the proximal end and the distal end of the expandable coaption portion to cause the expandable coaption portion to expand.

3725. The system of any one of claims 3119-3624, wherein the actuation member pulls on one of the proximal end and the distal end of the expandable coaption portion to cause the expandable coaption portion to expand.

3826. The system of any one of claims 3119-3624, wherein the actuation member pushes on one of the proximal end and the distal end of the expandable coaption portion and pulls on the other of the proximal end and the distal end of the expandable coaption portion to cause the expandable coaption portion to expand.

3927. The system of any one of claims 3419-3826, wherein the actuation member is a flexible actuation member that is routed through the distal end to the proximal end of the expandable coaption portion.

4028. The system of any one of claims 3419-3927, wherein the expandable coaption portion is attached to a proximal portion of the coaption element.

~~41. — The system of any one of claims 31-39, wherein the expandable coaption portion is attached to a distal portion of the coaption element.~~

4229. The system of any one of claims 3419-413628, further comprising a biasing member extending between the proximal end and the distal end of the expandable coaption portion that biases the expandable coaption portion toward the extended condition.

4330. The system of any one of claims 3419-4128, further comprising a biasing member extending between the proximal end and the distal end of the expandable coaption portion that biases the expandable coaption portion toward the retracted condition.

4431. The system of any one of claims 3419-4330, further comprising:

a locking member extending between the proximal end and the distal end of the expandable coaption portion; and

a lock that has a locked condition and an unlocked condition;

wherein in the unlocked condition, the lock allows the locking member to change length as the proximal and distal ends move together or apart; and

wherein in the locked condition, the lock prohibits the locking member to change length as the proximal and distal ends move together or apart.

4532. The system of any one of claims 3419-4431, wherein the actuation member comprises a rotatable cam member that is rotatable between a first position and a second position to cause the expandable coaption portion to expand from a retracted condition to an extended condition.

4633. The system of any one of claims ~~3119-4532~~, wherein the valve repair device comprises:

a shaft;

a collar that the shaft extends through, the collar being attached to the coaption element;

a cap attached to the shaft such that the cap can be moved by the shaft away from the collar; and

a plurality of paddle portions, wherein the paddle portions are moveable between an open position and a closed position and are configured to attach to the native valve of the patient;

wherein movement of the cap toward the collar causes the paddle portions to move to the closed position, and movement of the cap away from the collar causes the paddle portions to move to the open position.

4734. The system of any one of claims ~~3119-4633~~, wherein the shaft extends through expandable coaption portion.

4835. The system of any one of claims ~~46-33~~ and ~~4734~~, wherein the expandable coaption portion expands towards the paddle portions of the valve repair device.

4936. The system of any one of claims ~~3119-4835~~, wherein a width of the expandable coaption portion is inversely proportional to a length of the expandable coaption portion.

5037. The system of any one of claims ~~3119-4936~~, wherein the expandable coaption portion is formed from a tube of braided material.

~~51. — The system of any one of claims 31-50, wherein the expandable coaption portion is formed from a shape memory alloy.~~

~~52. — The system of any one of claims 31-50, wherein the expandable coaption portion is formed from an elastomeric material.~~

~~53. — The system of any one of claims 31-52, further comprising a cover extending over one or more of the coaption element and expandable coaption portions.~~

54. — The system of any one of claims 31–53, wherein the coaption element is configured to close a gap in the native valve of the patient when the valve repair device is attached to the native valve.

55. — A system for repairing a native valve of a patient, the system comprising:

a delivery catheter;

a valve repair device coupled to the delivery catheter, wherein the valve repair device comprises:

an expandable spacer assembly comprising:

a central shaft;

an actuation tube rotatably disposed around the central shaft;

an expandable spacer having a first end secured to the central shaft and a second end secured to the locking tube;

wherein rotation of the actuation tube relative to the central shaft causes the expandable spacer to expand.

56. — The system of claim 55, wherein a locking portion of the central shaft engages a locking portion of the expandable spacer to hold the spacer in a retracted position, an expanded position, and a plurality of positions between the retracted position and the expanded position.

57. — The system of claim 55 or claim 56, wherein a teeth of the central shaft engage teeth of the expandable spacer to hold the spacer in a retracted position, an expanded position, and a plurality of positions between the retracted position and the expanded position.

58. — The system of any one of claims 55–57, wherein a proximal end of the spacer is fixed to a proximal end of the shaft and a distal end of the spacer is fixed to a distal end of the actuation tube.

59. — The system of any one of claims 55–58, wherein the spacer comprises a tube with a plurality of cuts.

60. — ~~The system of any one of claims 55–59, wherein the spacer comprises a tube with a plurality of spiral shaped cuts.~~

61. — ~~A method of repairing a native valve of a patient, the method comprising:~~

~~placing a valve repair device in the heart of a patient;~~

~~expanding an expandable coaption portion outward through an opening in a coaption element;~~

~~engaging the expandable coaption portion with an actuation member to expand and retract the expandable coaption portion; and~~

~~anchoring the valve repair device to the native valve of the patient.~~

62. — ~~The method of claim 61, further comprising expanding the expandable coaption portion symmetrically through two openings in the coaption element.~~

63. — ~~The method of claim 61, further comprising expanding the expandable coaption portion asymmetrically through two openings in the coaption element such that a distal end of the expandable coaption portion extends to a greater width than a proximal end of the expandable coaption portion.~~

64. — ~~The method of claim 61, further comprising expanding the expandable coaption portion asymmetrically through two openings in the coaption element such that a proximal end of the expandable coaption portion extends to a greater width than a distal end of the expandable coaption portion.~~

65. — ~~The method of any one of claims 61, 63, and 64, further comprising:~~

~~extending a first expandable coaption portion through a first opening in the coaption element to a first distance; and~~

~~extending a second expandable coaption portion through a second opening in the coaption element to a second distance.~~

~~66. — The method of any one of claims 61–65, further comprising pushing on one of a proximal end and a distal end of the expandable coaption portion with the actuation member to cause the expandable coaption portion to expand.~~

~~67. — The method of any one of claims 61–65, further comprising pulling on one of the proximal end and the distal end of the expandable coaption portion with the actuation member to cause the expandable coaption portion to expand.~~

~~68. — The method of any one of claims 61–65, further comprising pushing on one of the proximal end and the distal end of the expandable coaption portion with the actuation member and pulling on the other of the proximal end and the distal end of the expandable coaption portion with the actuation member to cause the expandable coaption portion to expand.~~

~~69. — The method of any one of claims 61–68, further comprising routing the actuation member through the distal end to the proximal end of the expandable coaption portion.~~

~~70. — The method of any one of claims 61–69, further comprising attaching the expandable coaption portion to a proximal portion of the coaption element.~~

~~71. — The method of any one of claims 61–69, further comprising attaching the expandable coaption portion to a distal portion of the coaption element.~~

~~72. — The method of any one of claims 61–71, further comprising extending a biasing member between the proximal end and the distal end of the expandable coaption portion such that the expandable coaption portion is biased toward the extended condition.~~

~~73. — The method of any one of claims 61–71, further comprising extending a biasing member between the proximal end and the distal end of the expandable coaption portion such that the expandable coaption portion is biased toward the retracted condition.~~

~~74. — The method of any one of claims 61–73, further comprising:~~

~~— extending a locking member, having a locked condition and an unlocked condition, between the proximal end and the distal end of the expandable coaption portion; and~~

~~——changing the length of the locking member as the proximal and distal ends move together or apart when the locking member is in an unlocked condition; and~~

~~——prohibiting the locking member to change length as the proximal and distal ends move together or apart when the locking member is in a locked condition.~~

~~75.——The method of any one of claims 61–74, further comprising expanding the expandable coaption portion from a retracted condition to an extended condition by rotating a rotatable cam member between a first position and a second position.~~

~~76.——The method of any one of claims 61–75, further comprising moving a plurality of paddle portions between an open position and a closed position and attaching the paddle portions to the native valve of the patient.~~

~~77.——The method of claim 76, further comprising extending a shaft through the expandable coaption portion.~~

~~78.——The method of any one of claims 76 and 77, further comprising expanding the expandable coaption portion towards the paddle portions of the valve repair device.~~

~~79.——The method of any one of claims 61–78, wherein a width of the expandable coaption portion is inversely proportional to a length of the expandable coaption portion.~~

~~80.——The method of any one of claims 61–79, wherein the expandable coaption portion is formed from a tube of braided material.~~

~~81.——The method of any one of claims 61–80, wherein the expandable coaption portion is formed from a shape-memory alloy.~~

~~82.——The method of any one of claims 61–80, wherein the expandable coaption portion is formed from an elastomeric material.~~

~~83.——The method of any one of claims 61–82, further comprising extending a cover over one or more of the coaption element and expandable coaption portions.~~

84. — The method of any one of claims 61-83, further comprising closing a gap in the native valve of the patient with the coaption element when the valve repair device is attached to the native valve.

85. — A method of repairing a native valve of a patient, the method comprising:

placing a valve repair device in the heart of a patient;

providing an expandable spacer between two leaflets of the native valve; and

expanding the expandable spacer to fill a gap between the two leaflets of the native valve, wherein the gap is lateral to the spacer.

86. — The method of claim 85, further comprising engaging a locking portion of the expandable spacer with a locking portion of a central shaft to hold the expandable spacer in a retracted position, an expanded position, and a plurality of positions between the retracted position and the expanded position.

87. — The method of claim 85 or claim 86, further comprising engaging teeth of the central shaft with teeth of the expandable spacer to hold the spacer in a retracted position, an expanded position, and a plurality of positions between the retracted position and the expanded position.

88. — The method of any one of claims 85-87, wherein a proximal end of the expandable spacer is fixed to a proximal end of the central shaft and a distal end of the expandable spacer is fixed to a distal end of an actuation tube.

89. — The method of any one of claims 85-88, wherein the expandable spacer comprises a tube with a plurality of cuts.

90. — The method of any one of claims 86-89, wherein the expandable spacer comprises a tube with a plurality of spiral shaped cuts.