Claims

1. A split type precisely-anchorable transcatheter valve-in-ring system, characterized in that,

the system comprises a split transcatheter valve-in-ring anchoring stent and a transcatheter artificial biological valve-in-ring,

wherein the transcatheter valve-in-ring anchoring stent is customized to be personalized to supravalvular and subvalvular tissues of a patient's failed annuloplasty ring; a shape and structure of the transcatheter valve-in-ring anchoring stent are matched with a real structure of the annuloplasty ring and supravalvular and subvalvular tissues after three-dimensional reconstruction based on imaging data of the patient who have undergone valve failure after implantation of an annuloplasty ring, the transcatheter valve-in-ring anchoring stent is firstly delivered to the patient's failed annuloplasty ring for release, deformation and alignment with the supravalvular and subvalvular tissues of the failed annuloplasty ring;

the transcatheter artificial biological valve-in-ring is delivered to the transcatheter valve-in-ring anchoring stent for release, the stent of the transcatheter artificial biological valve-in-ring deforms and expands to the functional state of the transcatheter valve-in-ring, causing the transcatheter valve-in-ring anchoring stent to deform again and combine with the expanded transcatheter valve-in-ring, and meanwhile, the re-deformation of the transcatheter valve-in-ring anchoring stent causes the anchoring stent to combine with the subvalvular tissues again and anchor.

2. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 1, characterized in that, the re-combining anchor is a preset anchor for achieving a round shape.

3. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 1, characterized in that, further comprising a delivery assembly, wherein the delivery assembly comprises a transcatheter valve-in-ring anchoring stent delivery kit and a transcatheter valve-in-ring delivery kit, and the transcatheter valve-in-ring anchoring stent delivery kit comprises a delivery catheter and a transcatheter valve-in-ring anchoring stent loader.

4. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 1, characterized in that, the previously implanted annuloplasty rings refer to various types of mitral annuloplasty rings implanted for various etiologies of mitral valve insufficiency, or various types of

tricuspid annuloplasty rings implanted for various etiologies of tricuspid valve insufficiency; the shape and structure of the transcatheter valve-in-ring anchoring stent is accurately matched with the type of annuloplasty ring previously implanted and the personalized imaging data of postoperative valve failure through three-dimensional reconstruction of a real shape and anatomical structure; the transcatheter valve-in-ring anchoring stent and the transcatheter artificial biological valve-in-ring are sequentially inserted, and then reassembled into one in the body, the transcatheter valve-in-ring anchoring stent deforms again due to the release of the transcatheter valve, and completes the predetermined anchoring of the diseased mitral valve or tricuspid valve and subvalvular tissue in a regular circular shape, so that the transcatheter artificial biological valve-in-ring anchoring is protected from the stress of the shape of the previously implanted annuloplasty ring, and the persistent stability of the regular circular anchoring is obtained.

5. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 1, characterized in that, the transcatheter valve-in-ring is a mitral valve-in-ring and a tricuspid valve-in-ring.

6. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 3, characterized in that, the transcatheter valve-in-ring anchoring stent has a compressed state disposed in the delivery catheter, a first anchoring state after being released by the delivery catheter, and a second anchoring state after being combined with the transcatheter valve-in-ring,

in the first anchoring state, the valve-in-ring anchoring stent is released from the delivery catheter after being released by the delivery catheter, and is deformed and engaged with the supravalvular and subvalvular tissue of the patient’s failed annuloplasty ring;

in the second anchoring state, the valve-in-ring anchoring stent is subjected to secondary deformation via the transcatheter valve-in-ring, and is combined with the transcatheter valve-in-ring to complete the final anchoring and binding to the subvalvular tissue of the patient’s failed annuloplasty ring.

7. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 6, characterized in that, in the second anchoring state, the transcatheter artificial biological valve-in-ring is delivered by the delivery catheter to the first state of the transcatheter valve-in-ring anchoring stent for balloon expansion and release, the balloon expansion external force causes the valve-in-ring

anchoring stent to deform again, and it combines with the expanded transcatheter artificial biological valve-in-ring to form a body, to realize the preset anchoring of the anchoring stent with the valve leaflet and subvalvular tissue of the patient's mitral or tricuspid valve site in a preset circular shape.

8. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 6, characterized in that, in the first anchoring state, the transcatheter valve-in-ring anchoring stent is processed and shaped into a conical funnel shape with a large atrial surface and a small ventricular surface according to the type, shape and size of the implanted annuloplasty ring and the personalized image data after three-dimensional reconstruction, the transcatheter valve-in-ring anchoring stent is input and released through the delivery catheter and is adapted to adapt to the supravalvular and subvalvular tissue of the patient's failed mitral valve or tricuspid valve to perform personalized alignment bonding and docking to form a preset structure with a circular shape in a remodeling rule; in the second anchoring state, in the transcatheter valve-in-ring anchoring stent of the first anchoring state, the transcatheter artificial biological valve-in-ring is delivered through the delivery catheter and is released by the balloon expansion, and is combined with the transcatheter valve-in-ring anchoring stent to form a whole, so that the transcatheter valve-in-ring anchoring stent is expanded from the original conical funnel shape to a cylindrical shape together with transcatheter valve-in-ring, and the centripetal return clip generated by the secondary deformation is tightly combined with the transcatheter valve-in-ring to complete the preset anchoring with the mitral valve site or the tricuspid valve site and the subvalvular tissue of the patient.

9. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 1, characterized in that, the real structure of the three-dimensional reconstruction is a digital image model or a three-dimensional printed simulation entity model, and the real structure of the three-dimensional reconstruction is a virtual simulated three-dimensional image and corresponding three-dimensional printed simulated entity model after the digital conversion of CT, ultrasound, and MRI comprehensive images.

10. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 6, characterized in that, the valve-in-ring anchoring stent is an umbrella tubular stent structure, comprising an atrial surface, a ventricular surface, and an anchoring stent connecting part therebetween, and the anchoring stent connecting part therebetween, wherein the atrial surface is an

umbrella shape and has an umbrella shape matching with the real shape of the three-dimensional reconstruction of the atrial surface image data of the patient, which is a first lattice portion; the ventricular surface is a plurality of positioning hook loops precisely aligned with the leaflet boundary; the anchoring stent connecting part is a round opening funnel shape and has a second lattice portion.

11. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 10, characterized in that, the first anchoring state of the connecting part of the valve-in-ring anchoring stent is a shape-setting memory state in vitro of the stent after being delivered and released through the delivery catheter, the shape-setting memory state of the connecting part from the atrial surface to the ventricular surface has a contraction taper, with a taper of 5-45 degrees; the connecting part of the anchoring stent undergoes deformation and expansion, transforming from a first anchoring state to a cylindrical second anchoring state.

12. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 10, characterized in that, the positioning hook loop is a precise alignment match between two leaflets of the patient's mitral valve or three leaflets of the tricuspid valve.

13. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 10, characterized in that, in the first anchoring state of the transcatheter valve-in-ring anchoring stent, the positioning hook loop is released through the delivery catheter in advance of the atrial surface of the transcatheter valve-in-ring anchoring stent, and the valve leaflet junction position of the patient’s mitral valve or tricuspid valve matched with the positioning hook loop is inserted, so that the atrial surface of the positioning anchoring stent matches with the atrial shape of the patient; in the second anchoring state after the transcatheter valve-in-ring anchoring stent is deformed, the positioning hook loop and the periphery of the connecting part of the anchoring stent are filled between a coupling portion of the annuloplasty ring and the transcatheter valve-in-ring.

14. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 13, characterized in that, in the second anchoring state, the positioning hook loop is filled in the eccentric region of the previously implanted annuloplasty ring, so that the central axis of the connecting part of the valve-in-ring anchoring stent is coaxial with the center of the previously implanted annuloplasty rings.

15. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 10, characterized in that, the ventricular surface of the valve-in-ring anchoring stent has a plurality of anchoring hook loops, which extend from the connecting part to the ventricular surface and then are folded, so as to match with the shape of real subvalvular tissue of the three-dimensional reconstruction of the subvalvular image data of the patient's failed valve.

16. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 15, characterized in that, in the first anchoring state of the valve-in-ring anchoring stent, after the anchoring hook loop is released through the delivery catheter, the anchoring hook loop is aligned with the subvalvular tissue of the patient's failed annuloplasty ring, and in the second anchoring state of the valve-in-ring anchoring stent, the plurality of anchoring hook loops form the clamping portion by action of deformation and the resultant force of the atrial surface and the connecting part of the valve-in-ring anchoring stent, and a plurality of deformed anchoring hook loops are tightly combined with the leaflet and subvalvular tissue under the patient's failed annuloplasty ring.

17. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 16, characterized in that, the number of the anchoring hook loops is 2-9.

18. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 10, characterized in that, the atrial surface end portion of the connecting part of the valve-in-ring anchoring stent is provided with a plurality of fixed support rods or stent bends for embedding the transcatheter valve-in-ring stent, the fixed support rods or stent bends extend in the axial direction of the atrial surface, and the ends thereof are bent towards the axis of the anchoring stent.

19. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 10, characterized in that, the connecting part of the valve-in-ring anchoring stent is provided with a plurality of end centripetal bending portions for embedding the outflow end of the transcatheter valve-in-ring stent, and the atrial surface end portions of the connecting parts of the centripetal bending and ring valve-in-ring anchoring stent are provided with a plurality of fixed support rods or bending upper and lower commissures for embedding the atrial end of the transcatheter valve-in-ring stent and to form an integrated whole with the anchoring stent, ensuring that the transcatheter valve-in-ring releases zero displacement.

20. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 19, characterized in that, the number of the fixed support rods or stent bends is 3-12.

21. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 10, characterized in that, the first lattice portion and the second lattice portion of the valve-in-ring anchoring stent are formed by a unit lattice composed of a compressible rhombic lattice, a V-shaped lattice and / or a hexagonal or polygonal lattice, and the first lattice portion is adaptively connected to the second lattice portion.

22. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 10, characterized in that, an outer periphery of the first lattice portion is spaced 1-2 mm from an atrial wall of the patient.

23. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 10, characterized in that, an inner peripheral edge diameter of the second lattice portion matches an outer diameter of various corresponding size specifications of a transcatheter artificial biological valve-in-ring.

24. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 1, characterized in that, a layer of medical polymer film is coated on the surface of the valve-in-ring anchoring stent.

25. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 1, characterized in that, the connecting parts of the atrial surface, the ventricular surface and the anchoring stent of the valve-in-ring anchoring stent are three-dimensional forming structures or split connecting structures after laser integrated cutting.

26. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 1, characterized in that, the anchoring stent is a metallic material or a non-metallic material having shape-setting memory properties, and the anchoring stent is made of a nickel-titanium alloy material.

27. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 1, characterized in that, the transcatheter artificial biological valve-in-ring comprises a cobalt-chromium alloy stent which is radially compressible and can be expanded by a balloon and is in a cylindrical shape, or a nickel-titanium alloy stent which is radially compressible and self-expandable and has a cylindrical shape, and three fan-shaped leaflets arranged on the inner side of the stent,

wherein the three fan-shaped leaflets each have a free edge, an arc-shaped bottom edge and leaflet boundary connecting parts which extend on the two sides, and the stent is a metal net tube.

28. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 22, characterized in that, the valve frame is a cobalt-based alloy cobalt or chromium alloy or a nickel-titanium alloy.

29. The split type precisely-anchorable transcatheter valve-in-ring system according to claim 1, characterized in that, the transcatheter valve-in-ring anchoring stent delivery device and the transcatheter artificial biological valve-in-ring delivery device, for the tricuspid valve-in-ring, it can be approached from the inferior vena cava via the femoral vein, or from the superior vena cava via the jugular vein or subclavian vein to the tricuspid valve site; and for the mitral valve-in-ring, it can be approached through the apex of the heart, left atrium, or femoral vein via the interventricular septum to the mitral valve site.