Claims

1. A split type precisely-anchorable transcatheter artificial biological aortic valve system, characterized in that, the system comprises: a split transcatheter artificial biological aortic valve anchoring stent which is customized to be personalized to a patient's lesion aortic valve and a transcatheter artificial biological aortic valve, and the transcatheter artificial biological aortic valve comprises a stent and three leaflets;

wherein, a shape and structure of the transcatheter artificial biological aortic valve anchoring stent are matched with a real structure of an aortic valve after three-dimensional reconstruction according to patient's image data, the transcatheter artificial biological aortic valve anchoring stent is delivered to the patient's aortic valve site, released and deformed to be in alignment with the patient's aortic valve leaflet tissue and subvalvular tissue, that being a first deformation;

the transcatheter artificial biological aortic valve is delivered into the transcatheter artificial biological aortic valve anchoring stent for release, and the stent of the transcatheter artificial biological aortic valve deforms and expands the transcatheter artificial biological aortic valve to a functional state, causing the transcatheter artificial biological aortic valve anchoring stent to deform again and be embedded with the expanded transcatheter artificial biological aortic valve, and meanwhile, the transcatheter artificial biological aortic valve anchoring stent deforms and anchors again;

the transcatheter artificial biological aortic valve anchoring stent has a compressed state disposed in a catheter, a first anchoring state after being released by the catheter, and a second anchoring state after being combined with the transcatheter artificial biological aortic valve; in the first anchoring state when the first deformation occurs, the transcatheter artificial biological aortic valve anchoring stent is released and then deformed to be in alignment engagement with the patient's aortic valve leaflet and a subvalvular tissue of a corresponding inflow surface; and in the second anchoring state, the transcatheter artificial biological aortic valve anchoring stent undergoes secondary deformation via the transcatheter artificial biological aortic valve's expansion, and combines with the transcatheter artificial biological aortic valve to complete final anchoring and binding with the patient's aortic valvular tissue;

the transcatheter artificial biological aortic valve anchoring stent's first anchoring state is an umbrella tubular stent structure comprising a leaflet outflow surface, a leaflet inflow surface and a stent connecting part therebetween; and the leaflet outflow surface is two or three anchoring wire loops matching a real shape of three-dimensional reconstruction of image data of an outflow surface of the patient's leaflet; the leaflet inflow surface of the transcatheter artificial biological aortic valve anchoring stent is an anchoring wire loop corresponding to the anchoring wire loops of the leaflet outflow surface of the transcatheter

artificial biological aortic valve anchoring stent, which can form a structure that clamps the leaflets with the anchoring wire loops of the leaflet outflow surface of the transcatheter artificial biological aortic valve anchoring stent, with a shape matching a real shape of the three-dimensional reconstruction of aortic valve subvalvular image data; the stent connecting part of the transcatheter artificial biological aortic valve anchoring stent is a circular funnel-shaped lattice, an inner diameter of a formed circumference matches an outer diameter of the stent of the transcatheter artificial biological aortic valve after release;

the second anchoring state of the stent connecting part of the transcatheter artificial biological aortic valve anchoring stent is cylindrical with an inner peripheral diameter matched with an outer peripheral diameter of the transcatheter artificial biological aortic valve.

2. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 1, characterized in that, the aortic valve leaflet tissue is a leaflet and a leaflet root tissue of a valve inflow surface.

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

4. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 3, characterized in that the transcatheter artificial biological aortic valve is delivered into the transcatheter artificial biological aortic valve anchoring stent through a catheter for release, the stent of the transcatheter artificial biological aortic valve deforms and expands the transcatheter artificial biological aortic valve to a functional state, causing the transcatheter artificial biological aortic valve anchoring stent to deform again and be embedded with the expanded transcatheter artificial biological aortic valve, and meanwhile, the transcatheter artificial biological aortic valve anchoring stent deforms again, causing the transcatheter artificial biological aortic valve anchoring stent combines again with a lesion leaflet and a subvalvular tissue, so that the transcatheter artificial biological aortic valve anchoring stent forms a clamping portion with the leaflet and a corresponding inflow surface subvalvular tissue, and while re-anchoring, the transcatheter artificial biological aortic valve combined with it is limited.

5. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to any one of claims 1 to 4, characterized in that, a real structure of an aortic valve reconstructed in three-dimensions according to the patient’s image data is a digital image model or a three-dimensional printed simulation entity model.

6. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 5, characterized in that, a real structure of the aortic valve reconstructed in three- dimensions according to the patient's image data is an anatomical structure of a simulated aortic valve lesion, and its digital image model is a three-dimensional image model simulated by a comprehensive images digital conversion of CT, ultrasound, and MRI of the patient, and its simulated entity model is a corresponding 3D printed simulated entity model.

7. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 3, characterized in that, the leaflet outflow surface of the transcatheter artificial biological aortic valve anchoring stent is a telecentric outflow end, the leaflet inflow surface of the transcatheter artificial biological aortic valve anchoring stent is a proximal inflow end, the anchoring wire loop at an outflow end is a quasi-circular folding type of a lattice extension of the stent connecting part, and shape, size, and folding angle of the anchoring wire loop at the outflow end are matched with a lesion simulation shape according to three-dimensional reconstruction of the patient's image data; the anchoring wire loop at an inflow end is a quasi-circular small folding or a row of rhombic lattice structure, and shape, size, and folding or row of rhombic lattice structure of a circular small folding shape of the inflow end match a simulation shape and a peripheral diameter of a bottom of the aortic valve's inflow end leaflet three-dimensionally reconstructed according of the patient's image data;

the stent connecting part is a conical funnel-shaped lattice or three support rods connecting the inflow end and the outflow end, and a former taper matches an aortic valve simulation shape three-dimensionally reconstructed according to the patient's image data; and an actual length from a lower edge of a coronary opening in the patient's image to a bottom of a valve base at the inflow end of the aortic valve is a length of the stent connecting part.

8. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 7, characterized in that, in the first anchoring state, after the transcatheter artificial biological aortic valve anchoring stent is released through the catheter, the transcatheter artificial biological aortic valve anchoring stent is returned from a compressed state, the anchoring wire loop at the outflow end of the transcatheter artificial biological aortic valve anchoring stent is folded back to correspondingly extend to an annulus of the lesion aortic valve's leaflet of the patient and the quasi-circular small folding's anchoring wire loop corresponding to the inflow end is everted out of a bottom of the leaflet base of the inflow end of the lesion aortic valve, corresponding anchoring wire loops at two ends form an alignment clamping inside and outside the leaflet as well as up and down, and a lattice of the stent connecting part of the transcatheter artificial biological aortic valve anchoring stent is

released to be funnel-shaped at intersection of the lesion aortic valve's leaflets, so that the leaflet is in an approximately normal open-close state;

in the second anchoring state, the transcatheter artificial biological aortic valve delivered through the catheter and crimped into a strip shape in the first anchoring state enters the transcatheter artificial biological aortic valve anchoring stent to be released by a balloon dilation, and external force of the balloon dilation causes the transcatheter artificial biological aortic valve to expand from a strip shape to a cylindrical-shape functional state; and meanwhile, the transcatheter artificial biological aortic valve anchoring stent undergoes a secondary deformation from a funnel-shaped shape to a cylindrical shape, which is tightly combined with the transcatheter artificial biological aortic valve, and as a result, the secondary deformation of the transcatheter artificial biological aortic valve anchoring stent also re-anchors with the patient's lesion aortic valve leaflet and a root tissue of the leaflet attached to an aortic wall.

9. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 1, characterized in that, the outflow surface and the inflow surface of the stent connecting part of the transcatheter artificial biological aortic valve anchoring stent are both provided with fixed support rods or stent end bends for embedding in the stent of the transcatheter artificial biological aortic valve, a direction of the fixed support rods or stent end bends is axis bending, and when deformed to a cylindrical shape in the second anchoring state, distance between the fixed support rods or stent end bends at two ends of a leaflet outflow surface and a leaflet inflow surface of the stent connecting part of the transcatheter artificial biological aortic valve anchoring stent is matched with a height of the stent of the transcatheter artificial biological aortic valve.

10. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 9, characterized in that, two ends of the stent connecting part of the transcatheter artificial biological aortic valve anchoring stent are provided with a plurality of end centripetal hooks for embedding the outflow end of the stent of the transcatheter artificial biological aortic valve; the centripetal hooks surround up and down with fixed support rods or stent end bends provided at the inflow end of the stent connecting part of the transcatheter artificial biological aortic valve anchoring stent for embedding the inflow end of the transcatheter artificial biological aortic valve, thereby preventing displacement during releasing the transcatheter artificial biological aortic valve.

11. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 10, characterized in that, the number of the fixed support rods or stent end bends is 3 -12.

12. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 1, characterized in that the stent connecting part of the transcatheter artificial biological aortic valve anchoring stent is a unit lattice composed of a compressible diamond lattice or a V-shaped lattice, and the stent connecting part is adaptively connected to the anchoring wire loops at both ends.

13. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 1, characterized in that, an outer peripheral edge of an arc of the inflow end's anchoring wire loop of the transcatheter artificial biological aortic valve anchoring stent is closely attached to a lower root of the patient's aortic valve.

14. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 1 or 2, characterized in that, a surface of the transcatheter artificial biological aortic valve anchoring stent is coated with a layer of medical polymer film.

15. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 1 or 2, characterized in that, the transcatheter artificial biological aortic valve anchoring stent is a three-dimensional forming structure or a separate connecting structure after laser integrated cutting.

16. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 1 or 2, characterized in that, the transcatheter artificial biological aortic valve anchoring stent is made of a nickel-titanium alloy material.

17. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 3, characterized in that the stent of the transcatheter artificial biological aortic valve comprises a cobalt-chromium alloy stent which is radially compressible and can be expanded to a cylindrical shape by a balloon dilation, or a nickel-titanium alloy stent which is radially compressible and self-expanding to a cylindrical shape; the three leaflets are three fan-shaped leaflets arranged on an inner side of the stent of the transcatheter artificial biological aortic valve; the three leaflets each has a free edge, an arc-shaped bottom edge and leaflet boundary connecting parts which extend on two sides, and the stent of the transcatheter artificial biological aortic valve is a metal net tube.

18. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 17, characterized in that, the stent of the transcatheter artificial biological aortic valve is a cobalt-based alloy cobalt or chromium alloy or a nickel-titanium alloy.

19. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 17, characterized in that, the transcatheter artificial biological aortic valve anchoring stent is firstly delivered into the lesion aortic valve's position through a

delivery catheter and released into the first anchoring state, and then the transcatheter artificial biological aortic valve is delivered to the transcatheter artificial biological aortic valve anchoring stent through a transcatheter artificial biological aortic valve delivery kit; as the transcatheter artificial biological aortic valve is expanded, the transcatheter artificial biological aortic valve anchoring stent is expanded to the second anchoring state fitting the transcatheter artificial biological aortic valve, and further tight combination with the perivalvular and subvalvular tissue is completed to form a final anchoring.

20. The split type precisely-anchorable transcatheter artificial biological aortic valve system of claim 4, characterized in that, the transcatheter artificial biological aortic valve delivery kit comprises a transcatheter artificial biological aortic valve delivery device, a guide sheath, a valve holder, and a charging pump.

21. The split type precisely-anchorable transcatheter artificial biological aortic valve system according to claim 1, characterized in that, the system is inserted through a femoral artery, carotid artery, subclavian artery, or apical puncture, and the transcatheter artificial biological aortic valve anchoring stent and the transcatheter artificial biological aortic valve can be inserted through the same pathway sequentially, or through different pathways sequentially.