Claims

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

the system comprises a split transcatheter tricuspid valve anchoring stent and a transcatheter artificial biological tricuspid valve,

wherein a shape and structure of the transcatheter tricuspid valve anchoring stent are matched with a tricuspid valve's real structure after a patient's image data is subjected to three-dimensional reconstruction, the transcatheter tricuspid valve anchoring stent is firstly delivered to a tricuspid valve site of the patient to be released, deformed and personalized and precise alignment with a supravalvular and subvalvular tissue of the patient's tricuspid valve site;

the transcatheter artificial biological tricuspid valve is delivered into the transcatheter tricuspid valve anchoring stent to be released, the transcatheter artificial biological tricuspid valve is released and deformed and expanded to a functional state, the transcatheter tricuspid valve anchoring stent is deformed again to be combined with the expanded transcatheter artificial biological tricuspid valve, and meanwhile, re-deformation of the transcatheter tricuspid valve anchoring stent is anchored by the combination of the transcatheter tricuspid valve anchoring stent and the subvalvular tissue in advance.

2. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 1, characterized in that, the tricuspid valve system further comprises a delivery assembly, the delivery assembly comprises a transcatheter tricuspid valve anchoring stent delivery set and a transcatheter artificial biological tricuspid valve delivery set, and the transcatheter tricuspid valve anchoring stent delivery set comprises a delivery catheter and a transcatheter tricuspid valve anchoring stent delivery device.

3. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 1, characterized in that, the split type transcatheter tricuspid valve anchoring stent and the transcatheter artificial biological tricuspid valve are respectively in an anterior and posterior approach, and then reassembled into one in vivo, and

meanwhile, the transcatheter tricuspid valve anchoring stent is deformed again to be combined with the tricuspid valve and the subvalvular tissue of the patient's lesion in advance to achieve anchoring of the transcatheter artificial biological tricuspid valve, so as to replace the tricuspid valve of the lesion in situ.

4. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 1, characterized in that, the transcatheter tricuspid valve 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 artificial biological tricuspid valve,

in the first anchoring state, the transcatheter tricuspid valve anchoring stent is released by the delivery catheter and then deformed to be in personalized precise alignment and engagement and clamping of the supravalvular and subvalvular tissue of the patient's tricuspid valve site;

in the second anchoring state, the transcatheter artificial biological tricuspid valve is delivered into the transcatheter tricuspid valve anchoring stent in the first state by the delivery catheter to expand a secondary deformation by balloon expandable external force, and it is integrated with the expanded transcatheter artificial biological tricuspid valve to complete anchoring of the transcatheter tricuspid valve anchoring stent and a leaflet or subvalvular tissue of the tricuspid valve site of the patient in advance.

5. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 4, characterized in that,

in the first anchoring state, the transcatheter tricuspid valve anchoring stent is processed and shaped into a funnel shape with a large atrial surface and a small ventricular surface, and deformation and return of the transcatheter tricuspid valve anchoring stent after being inputted and released through the delivery catheter adapt to the tricuspid valve's supravalvular and subvalvular tissue of the patient's dynamic lesion and personalized alignment engagement and clamping is implemented;

in the second anchoring state, the transcatheter tricuspid valve anchoring stent in the first anchoring state and the transcatheter artificial biological tricuspid valve is delivered into the transcatheter tricuspid valve anchoring stent via the delivery catheter,

which is expanded by balloon and integrated together, so that the transcatheter tricuspid valve anchoring stent is held byan original funnel shape together with the transcatheter artificial biological tricuspid valve into a cylindrical secondary deformation to generate centripetal return clip, and tight combination of the tricuspid valve site and subvalvular tissue of the patient is completed.

6. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 1, characterized in that, a real structure of the three-dimensional reconstruction is a digital image model or a three-dimensional printed simulation entity model; a real structure of the three-dimensional reconstruction is a three-dimensional image of a virtual simulation after digital conversion of CT, ultrasonic and nuclear magnetic integrated images and a corresponding three-dimensional printing simulation entity model.

7. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 4, characterized in that,

the transcatheter tricuspid valve anchoring stent is an umbrella tubular stent structure, comprising an atrial surface, a ventricular surface and an anchoring stent connecting part therebetween, wherein the atrial surface is an umbrella sheet, and has an umbrella shape matching a real personalized shape of the three-dimensional reconstruction of the image data of the atrial surface of the patient, that is, the ventricular surface is a first lattice portion; the ventricular surface is three positioning hook loops which are precisely preset with boundary positions of an anterior leaflet, a septum and posterior leaflet of the tricuspid valve of the patient; the anchoring stent connecting part is a circular funnel shape having a circular opening diameter and an inner diameter of tricuspid valve rings of the patient and an outer diameter of the transcatheter artificial biological tricuspid valve, and the second lattice portion of a lower opening of the funnel that matches shape and degree of tricuspid valve stenosis and /or regurgitation lesions.

8. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 7, characterized in that, the first anchoring state of the anchoring stent connecting part is a three-dimensional shape-memory state of a real anatomical shape and structure of the patient after delivery and release of the delivery catheter, a

shape-memory state of the anchoring stent connecting part from the atrial surface to the ventricular surface has a contraction taper, the taper is 5-45 degrees, the anchoring stent connecting part is deformed and expanded to form a cylindrical second anchoring state from a conical funnel-shaped deformation of the first anchoring state depending on a shape of the lesion leaflet of the patient.

9. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 8, characterized in that, in the first anchoring state of the transcatheter tricuspid valve anchoring stent, after the positioning hook loops are released through the delivery catheter, the positioning hook loops are inserted into a junction position of the anterior leaflet, the septum and the posterior leaflet of the tricuspid valve of the patient's lesion matched with the positioning hook loops, so as to realize personalized corresponding placement of the atrial surface of a positioning anchoring stent and the right atrium of the patient.

10. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 7, characterized in that, the ventricular surface of the transcatheter tricuspid valve anchoring stent has a plurality of anchoring hook loops, and the anchoring hook loops extend from the anchoring stent connecting part to the ventricular surface and then be folded, so as to accurately match the number of morphological contours of a real chordae tendineae and subvalvular tissue structure shape of the three-dimensional reconstruction of the subvalvular image data of the patient's lesion.

11. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 10, characterized in that, number, size, shape and folding angle of the anchoring hook loops are personalized and accurately matched with a real chordae tendineae gap, size and shape of the tricuspid valve's leaflet, and circumferential spacing of the perivalvular tissue from a ventricular wall in three dimensions of the three-dimensional reconstruction of the subvalvular image data of the tricuspid valve of the patient's lesion.

12. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 10, characterized in that, in the first anchoring state of the transcatheter tricuspid valve anchoring stent, after the anchoring hook loops are released

through the delivery catheter, the anchoring hook loops are positioned in the patient's chordae tendineae and the chordae tendineae's gap position to engage in a numerical alignment; in the second anchoring state of the transcatheter tricuspid valve anchoring stent, the plurality of anchoring hook loops form a clamping portion through a combined force of a return shape after being released and the atrial surface and the anchoring stent connecting part, a plurality of deformed anchoring hook loops are tightly intertwined with the leaflet and subvalvular chordae tendineae and the subvalvular tissue of the tricuspid valve of the patient's lesion.

13. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 10, characterized in that, three leaflets corresponding to the anchoring hook loops are divided into 3 groups, and the number of the anchoring hook loops in each group is 3-9, which corresponds to the number of chordae tendineae and chordae tendineae gaps.

14. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 7, characterized in that, the atrial surface's end portion of the anchoring stent connecting part of the transcatheter tricuspid valve anchoring stent is provided with a plurality of fixed support rods for embedding the transcatheter tricuspid valve stent, and the fixed support rods are bent along an axial direction of the atrial surface and ends thereof bend toward an axis of the transcatheter tricuspid valve anchoring stent.

15. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 14, characterized in that, the anchoring stent connecting partis provided with a plurality of end centripetal bending hooks for embedding an outflow end of the transcatheter tricuspid valve stent, the centripetal bending hooks and the plurality of fixed support rods form upper and lower coaptation, and a ventricular side can be prevented from being displaced when the transcatheter artificial biological tricuspid valve is released.

16. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 14, characterized in that, in the first anchoring state of the transcatheter tricuspid valve anchoring stent, the fixed support rods maintain an angle

consistent with the anchoring stent connecting part, and in the second anchoring state of the transcatheter tricuspid valve anchoring stent, the plurality of fixed support rods are axially parallel to coaptation circumference, so that an end of the fixed support rod is embedded on a stent of an inflow end of the transcatheter artificial biological tricuspid valve, and structurally integrated with the transcatheter artificial biological tricuspid valve to realize zero displacement when releasing the transcatheter artificial biological tricuspid valve.

17. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 14, characterized in that, the number of the fixed support rods is 3-12.

18. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 7, characterized in that, the first lattice portion and the second lattice portion of the transcatheter tricuspid valve anchoring stent are formed of a unit lattice composed of a compressible diamond 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.

19. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 7, characterized in that, an outer periphery of the lattice portion of the atrial surface of the transcatheter tricuspid valve anchoring stent is spaced apart from an atrial wall of the patient by 1-2 mm.

20. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 7, characterized in that, an inner peripheral edge diameter of the second lattice portion of the transcatheter tricuspid valve anchoring stent is matched with an outer diameter of various corresponding size specifications of the transcatheter artificial biological tricuspid valve.

21. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 1, characterized in that, a surface of the transcatheter tricuspid valve anchoring stent is partially or completely coated with a layer of medical polymer film.

22. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 1, characterized in that, the atrial surface, the ventricular surface and

the anchoring stent connecting part are three-dimensional shaped structures formed by laser integrated cutting or the atrial surface, the ventricular surface and the anchoring stent connecting part are reconnected after a split processing.

23. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 1, characterized in that, the transcatheter tricuspid valve anchoring stent is a metallic material or a non-metallic material having shape-memory reshape properties.

24. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 1, characterized in that, the transcatheter tricuspid valve anchoring stent is made of a nickel-titanium alloy material.

25. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 4, characterized in that, the transcatheter artificial biological tricuspid valve comprises a radially compressible cobalt-chromium alloy stent which can be expanded after balloon expansion, or a radially compressible self-expanding nickel-titanium alloy stent, and three fan-shaped leaflets arranged on an inner side of the stent, any of the fan-shaped leaflets has a free edge, an arc-shaped bottom edge and leaflet boundary connecting parts extending on two sides, and the stent is a metal net tube or a valve stent which can support three commissures of three leaflet interfaces and can be crimped.

26. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 25, characterized in that, the valve stent is a cobalt-based alloy cobalt or chromium alloy or a nickel-titanium alloy.

27. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 2, characterized in that, the transcatheter artificial biological tricuspid valve delivery set comprises a transcatheter artificial biological tricuspid valve delivery device, a guide sheath, a valve holder, and a charging pump.

28. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 27, characterized in that, the transcatheter tricuspid valve anchoring stent delivery device and the transcatheter artificial biological tricuspid valve delivery

device can be delivered from an inferior vena cava via the femoral vein, or from a superior vena cava via a jugular vein or subclavian vein to the tricuspid valve site.

29. The split type precisely-anchorable transcatheter tricuspid valve system according to claim 25, characterized in that, the transcatheter tricuspid valve anchoring stent is firstly guided into a diseased tricuspid valve site of the patient through the delivery catheter and released into the first anchoring state, and then the transcatheter artificial biological tricuspid valve is sent into the transcatheter tricuspid valve anchoring stent through the delivery catheter, and as the transcatheter artificial biological tricuspid valve is expanded, the transcatheter tricuspid valve anchoring stent is expanded to the second anchoring state, and meanwhile, the anchoring stent connecting part and the transcatheter artificial biological tricuspid valve are fitted and the ventricular surface of the transcatheter tricuspid valve anchoring stent completes further tight combination with the subvalvular tissue to form final anchoring.