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(54) **MEDICAL DEVICE AND IMPLANT SYSTEM**

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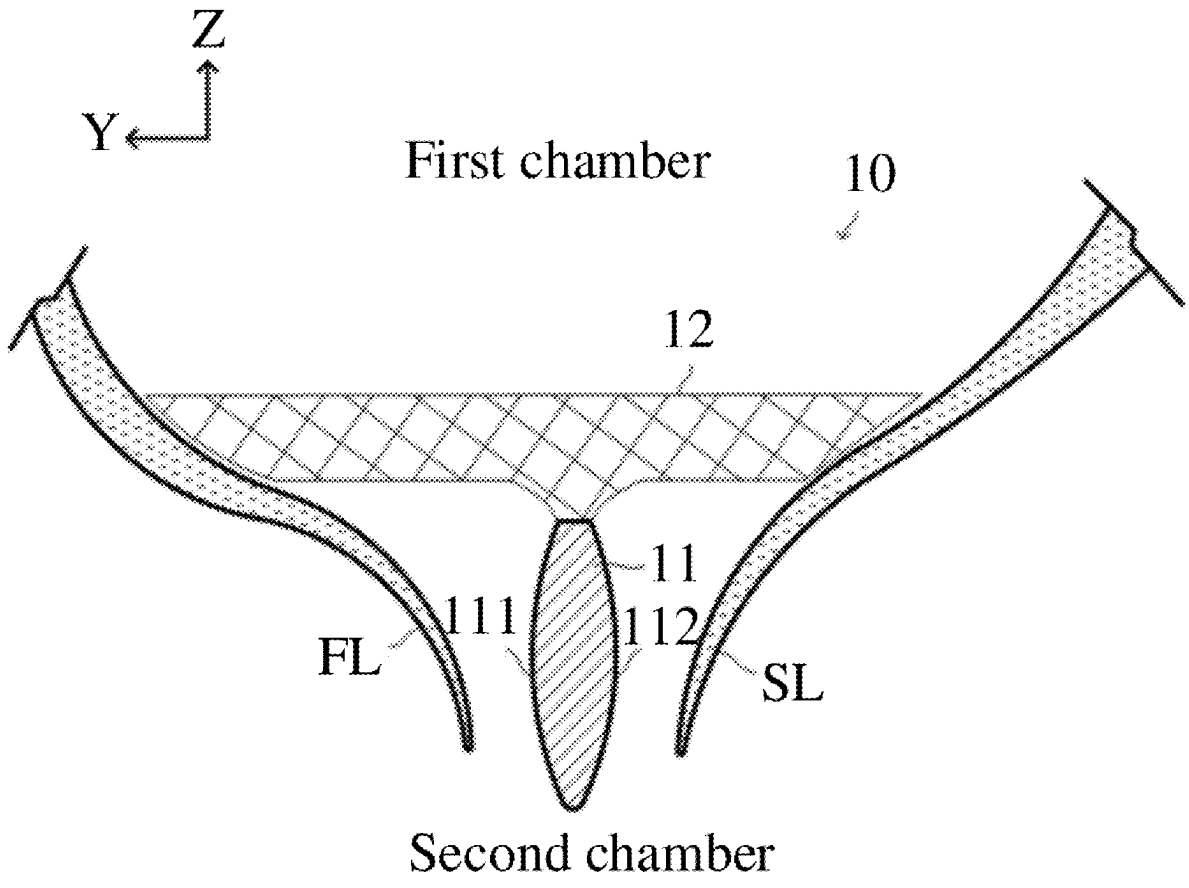
(57) **ABSTRACT**

Disclosed is a medical device for improving a function of a valve of a patient. This valve includes a plurality of leaflets. The medical device includes a pad configured to be positioned among the plurality of leaflets of the valve, to make the valve periodically open and close by cooperating with the plurality of leaflets. Via the pad located among the plurality of leaflets, the medical device provided by the present disclosure is able to improve a closure condition of the valve, so that the valve is able to close properly, and thus regurgitation of blood is effectively prevented or reduced.



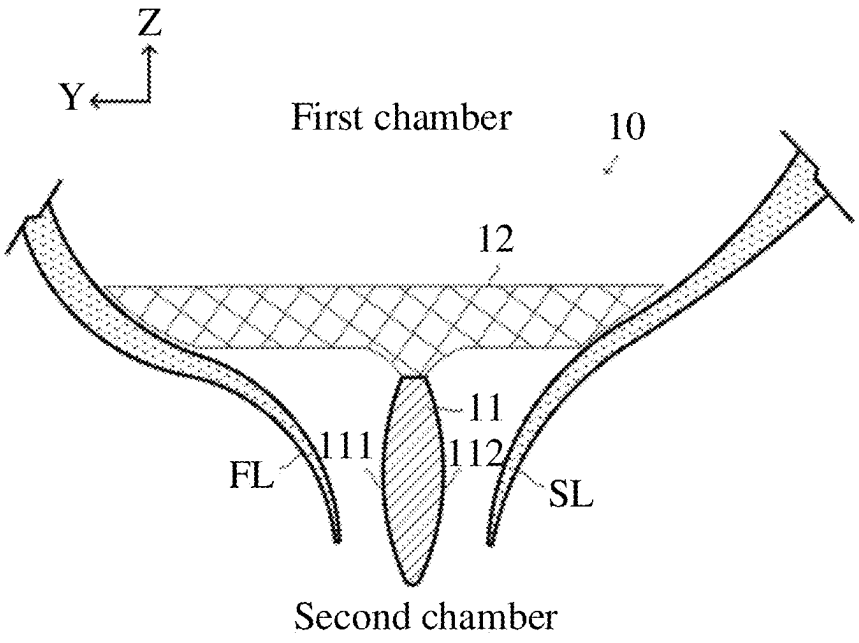

Z
Y
First chamber
10
12
11
111
112
FL
SL
Second chamber

FIG. 1

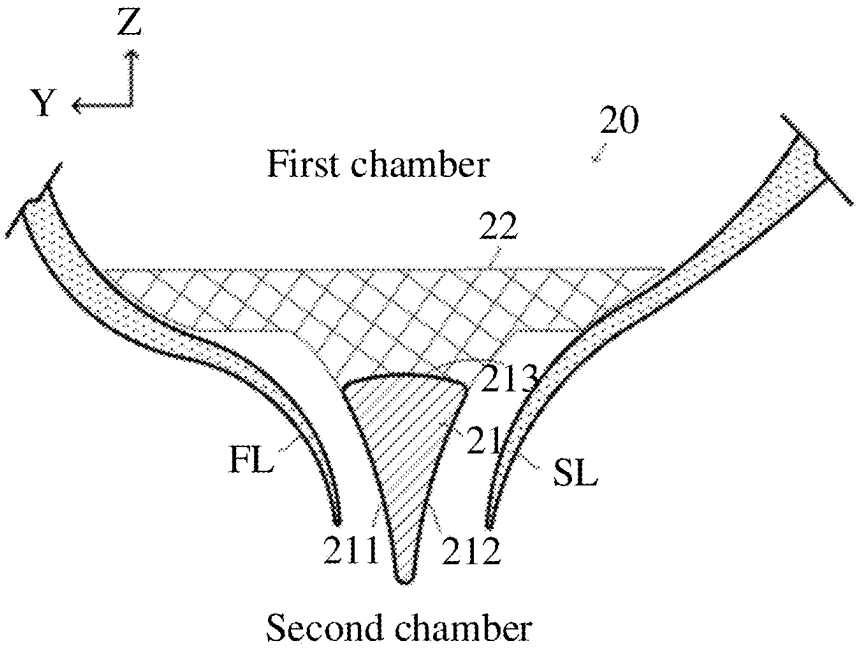

Z
Y
First chamber
20
22
213
21
FL
SL
211
212
Second chamber

FIG. 2

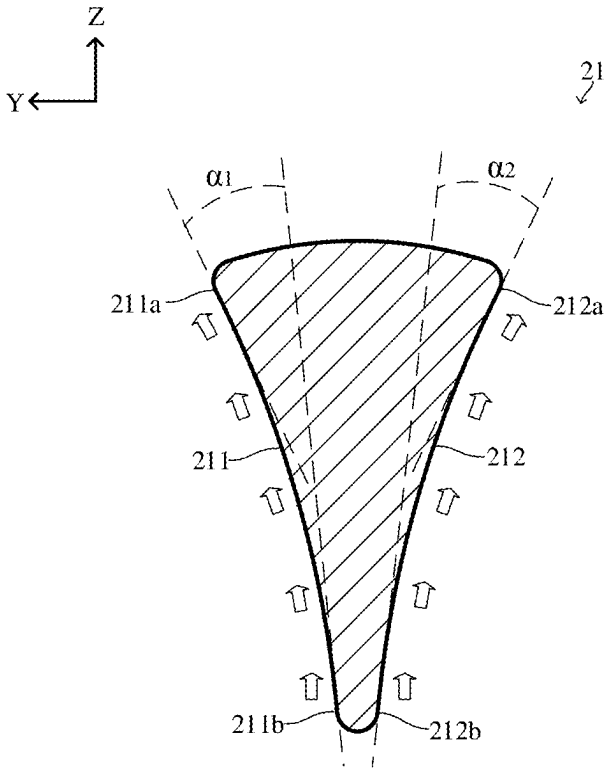


FIG. 3A

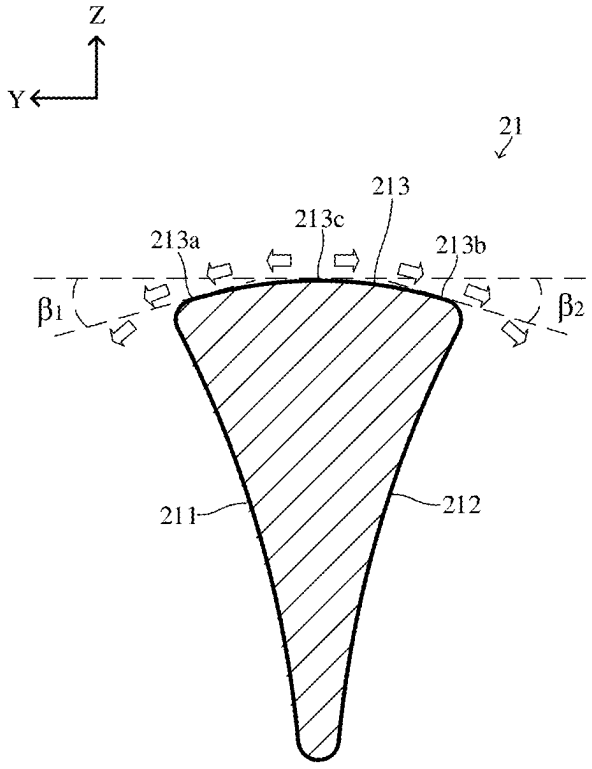


FIG. 3B

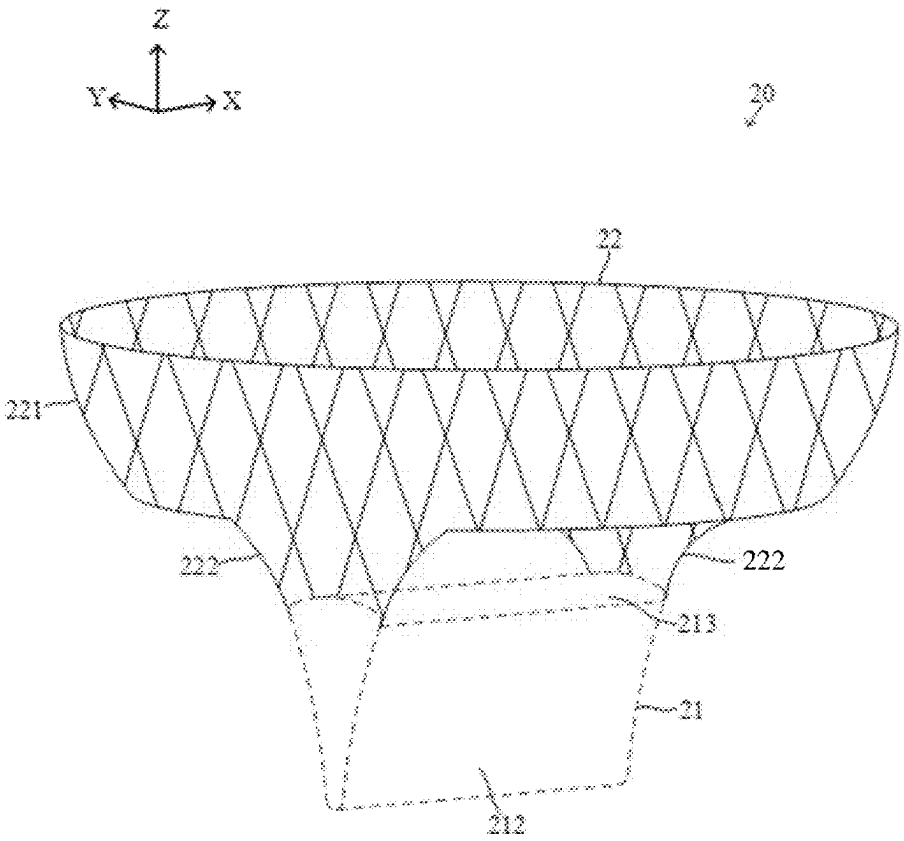


FIG. 4

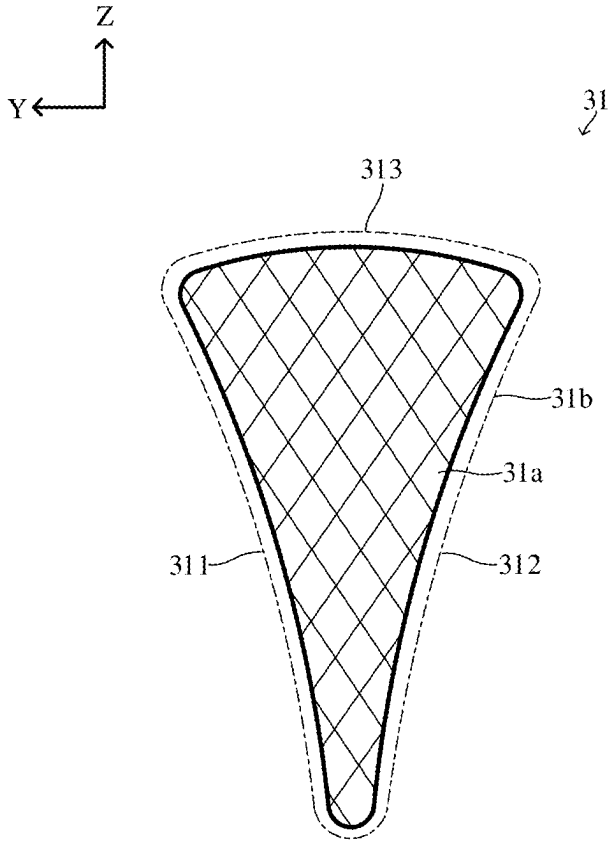


FIG. 5

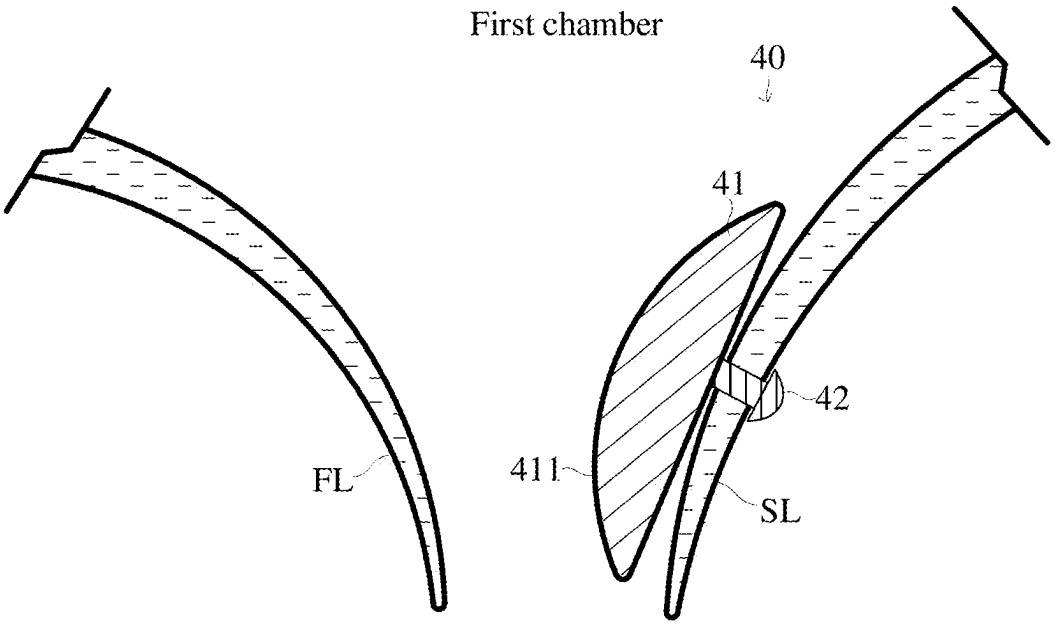


FIG. 6

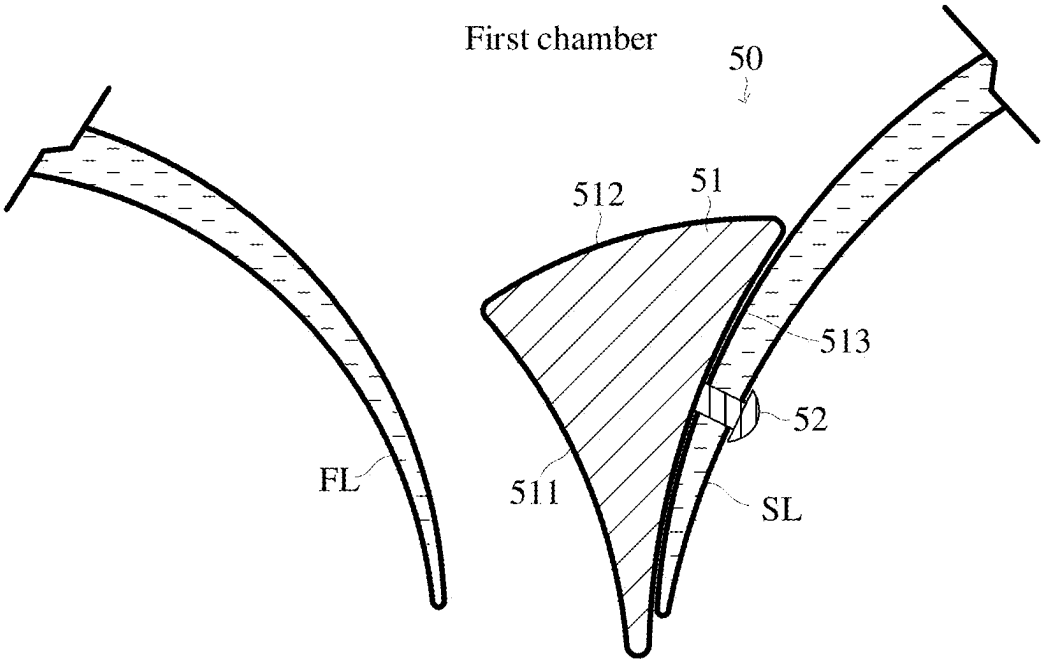


FIG. 7

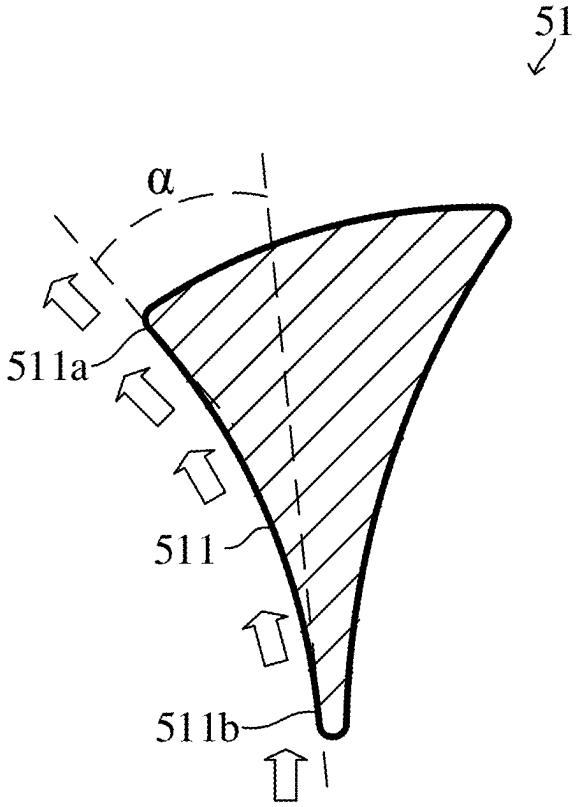


FIG. 8A

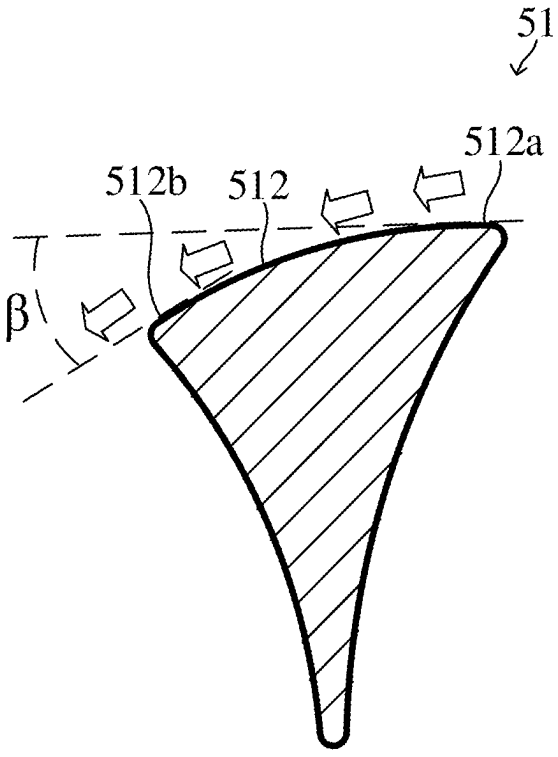


FIG. 8B

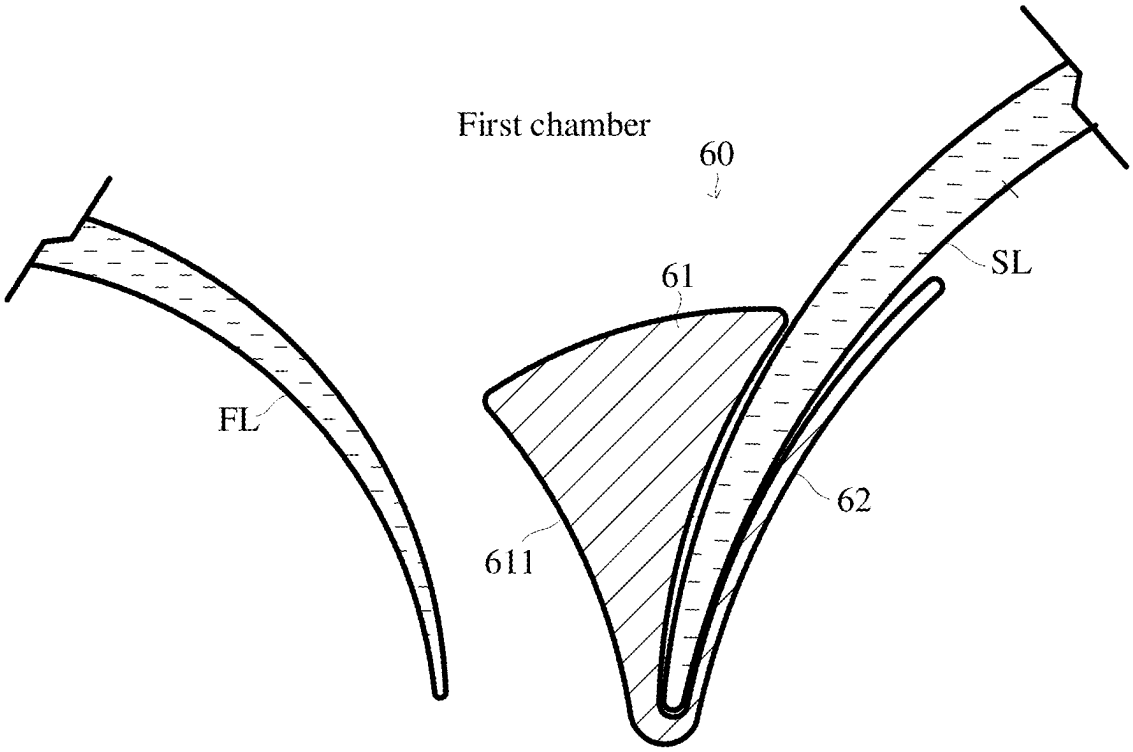


FIG. 9

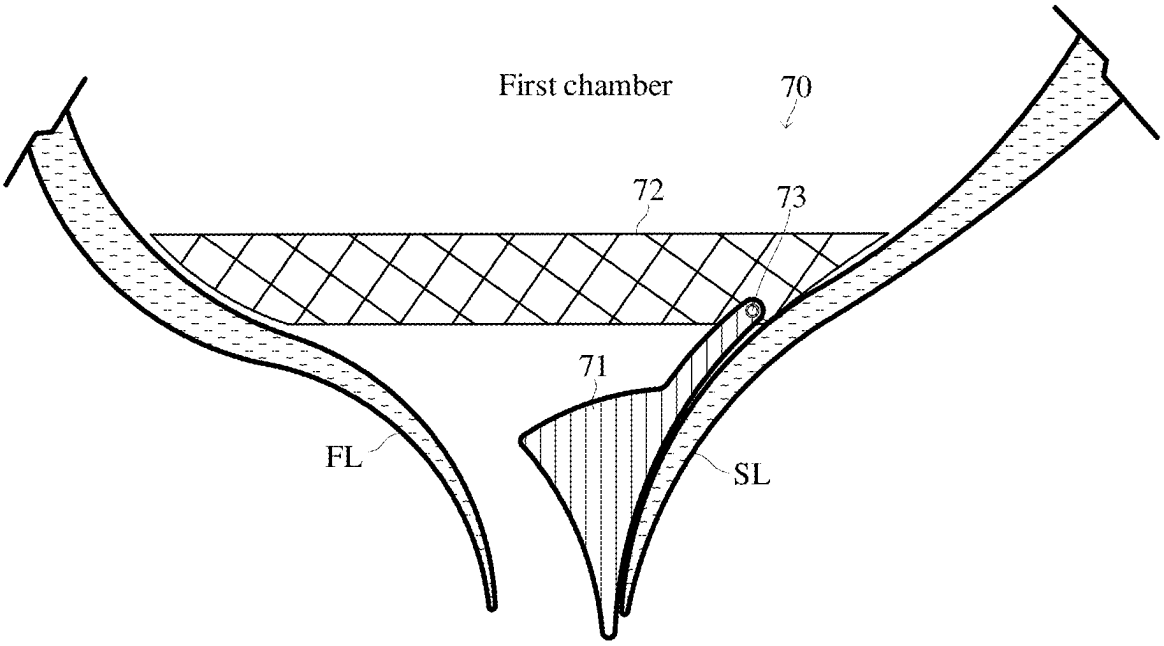


FIG. 10

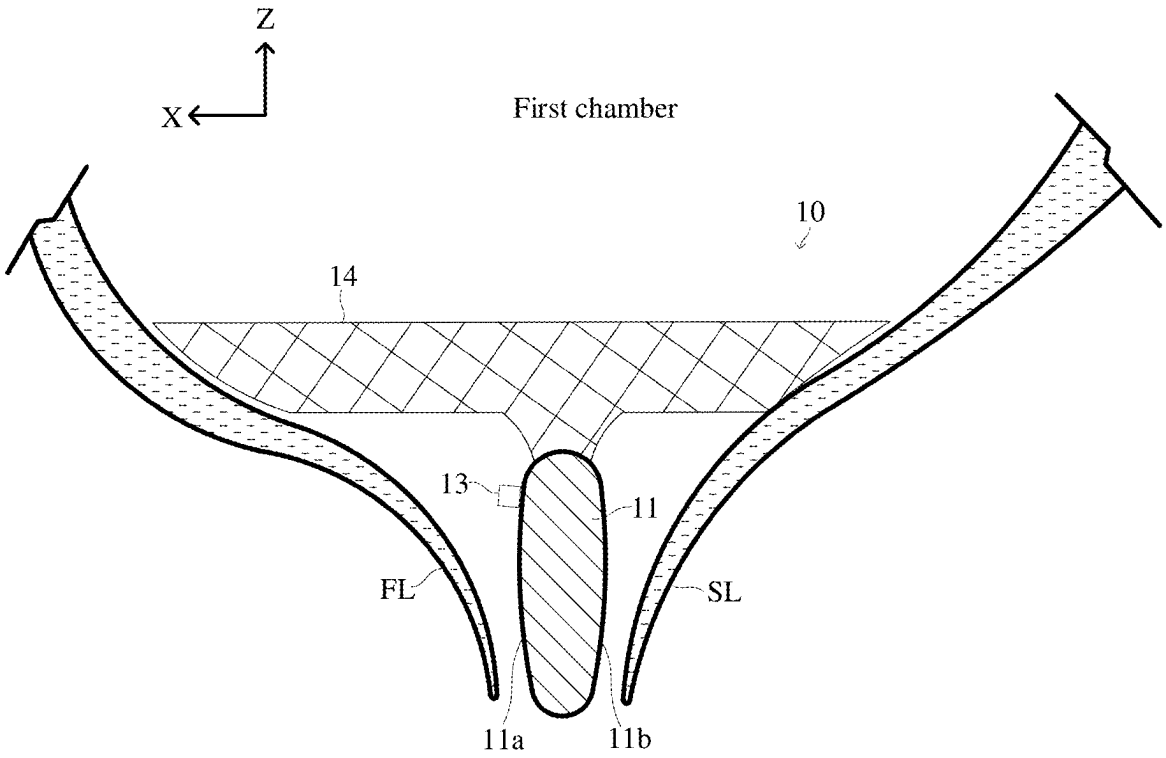


FIG. 11

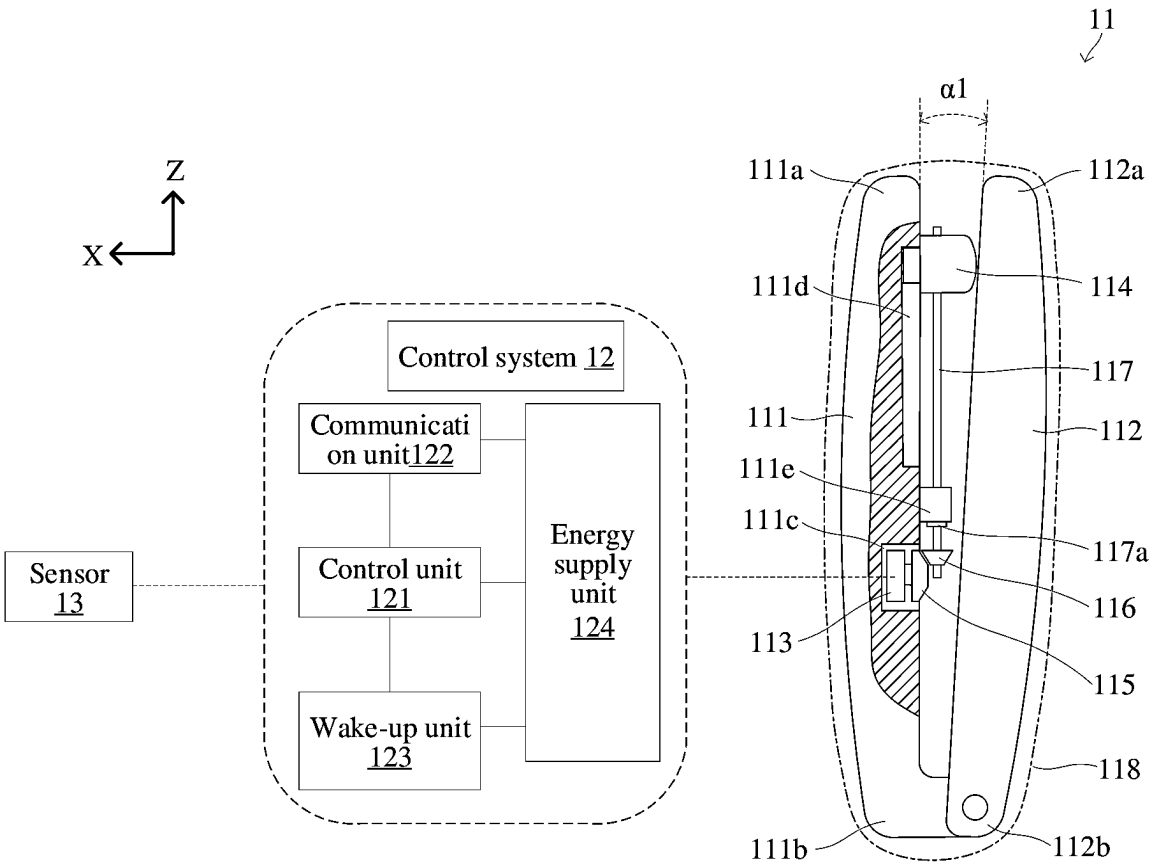

11
α1
Z
X
111a
112a
111d
114
117
111
112
111e
111c
117a
116
113
115
118
111b
112b
Control system 12
Communicati on unit122
Control unit 121
Wake-up unit 123
Energy supply unit 124
Sensor 13

FIG. 12A

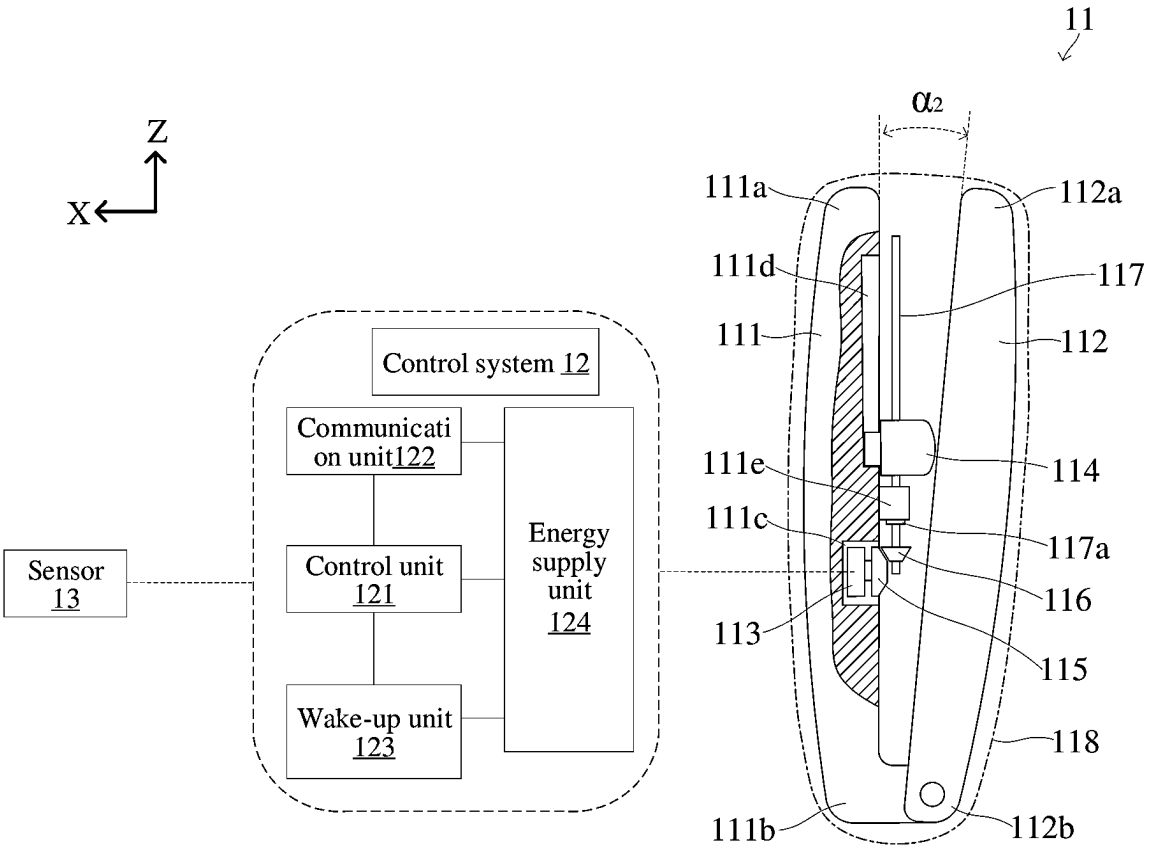

11
Z
X
α2
111a
112a
111d
117
111
112
111e
114
111c
117a
116
113
115
118
111b
112b
Control system 12
Communicati on unit122
Control unit 121
Wake-up unit 123
Energy supply unit 124
Sensor 13

FIG. 12B

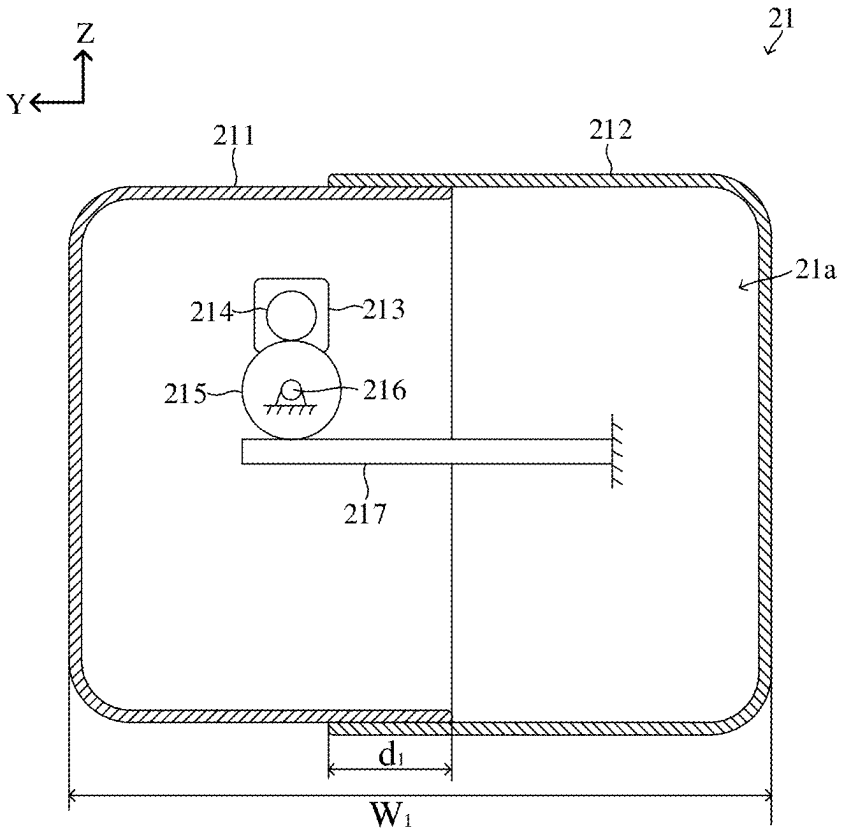


FIG. 13A

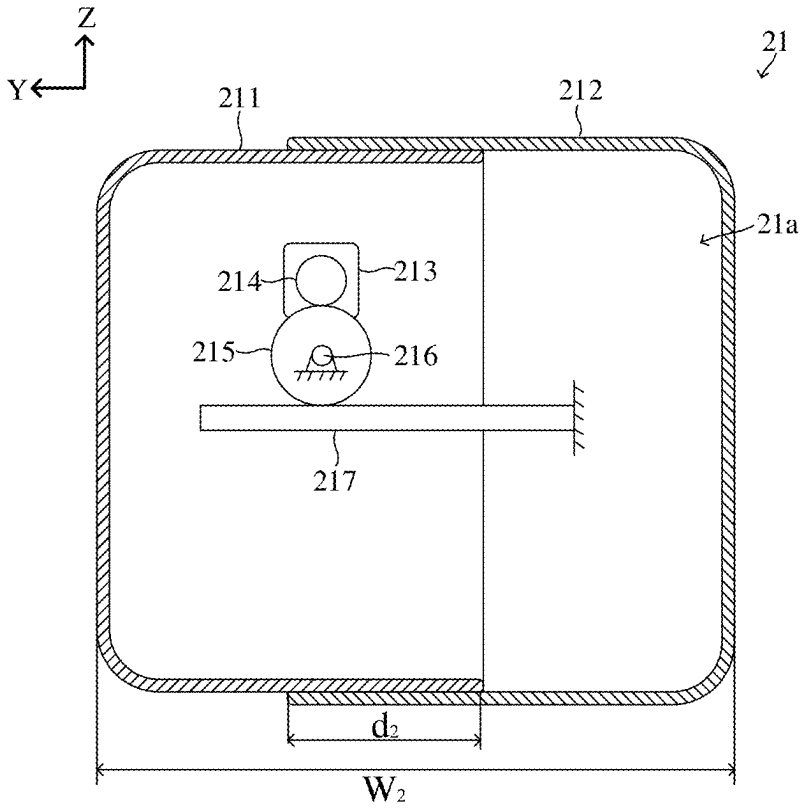


FIG. 13B

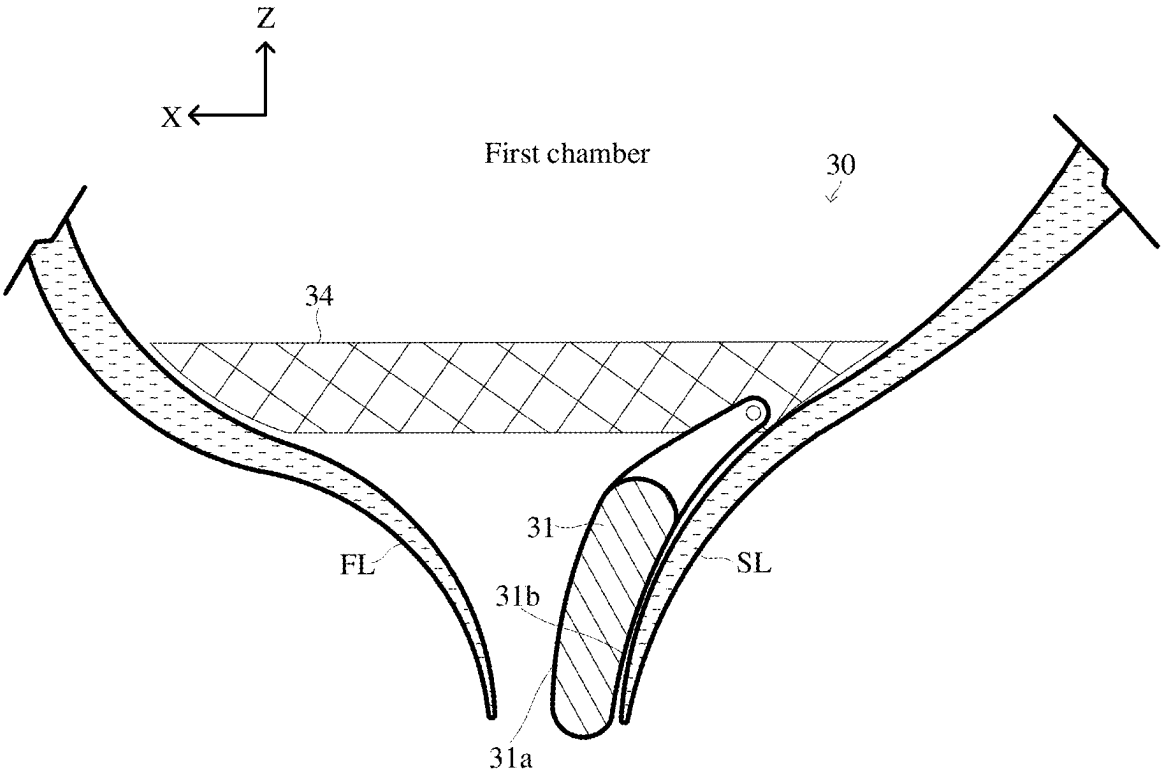


FIG. 14

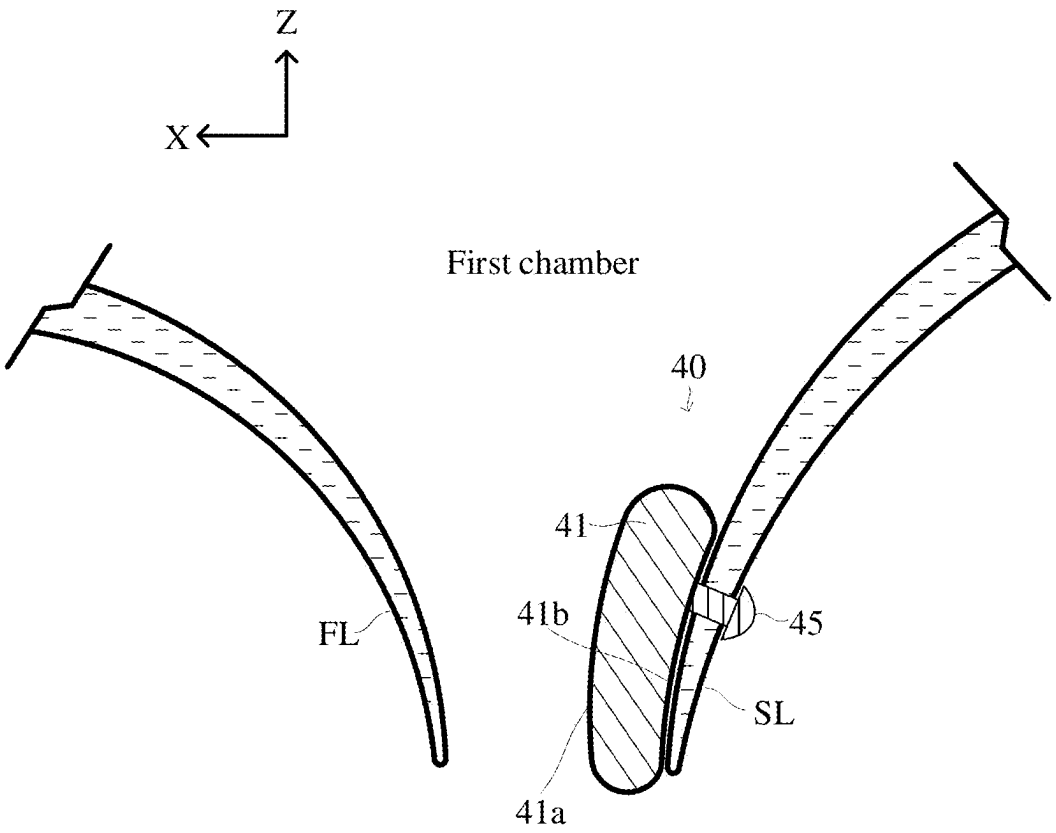


FIG. 15

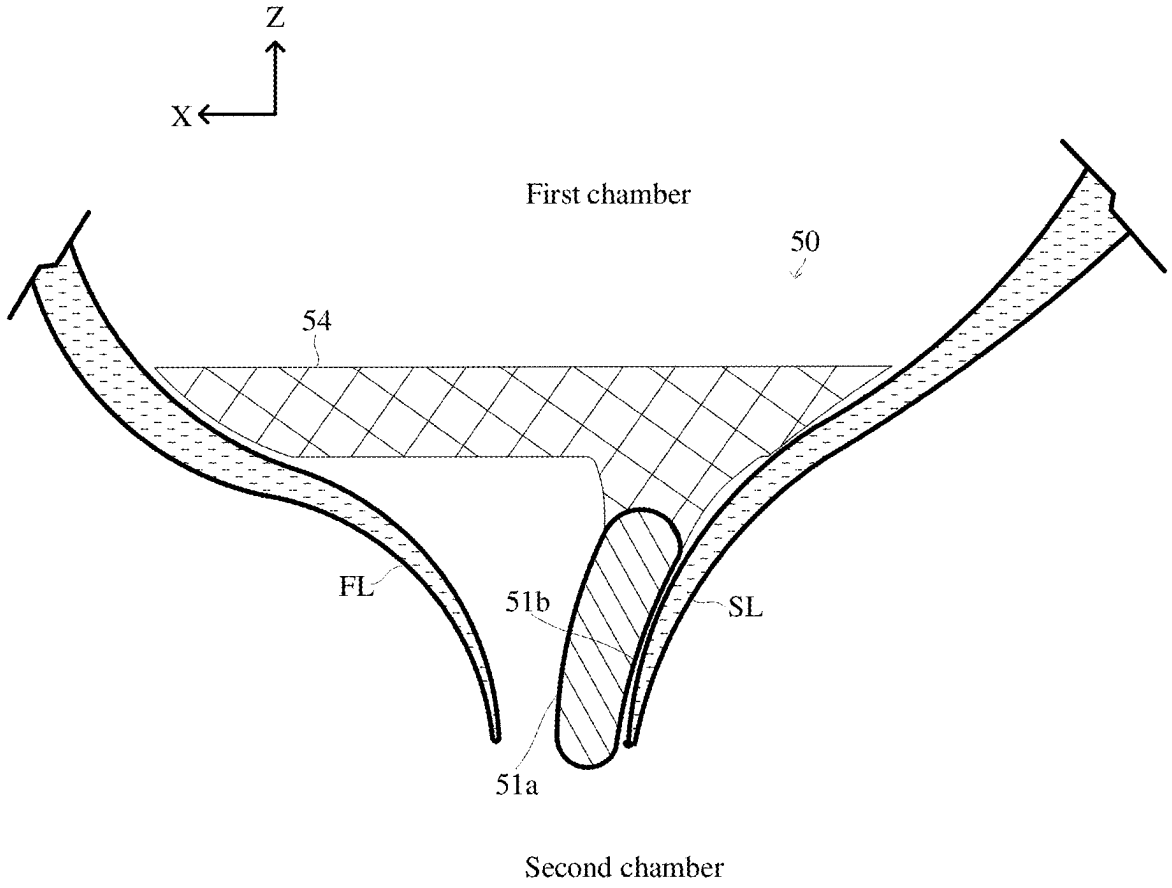


FIG. 16

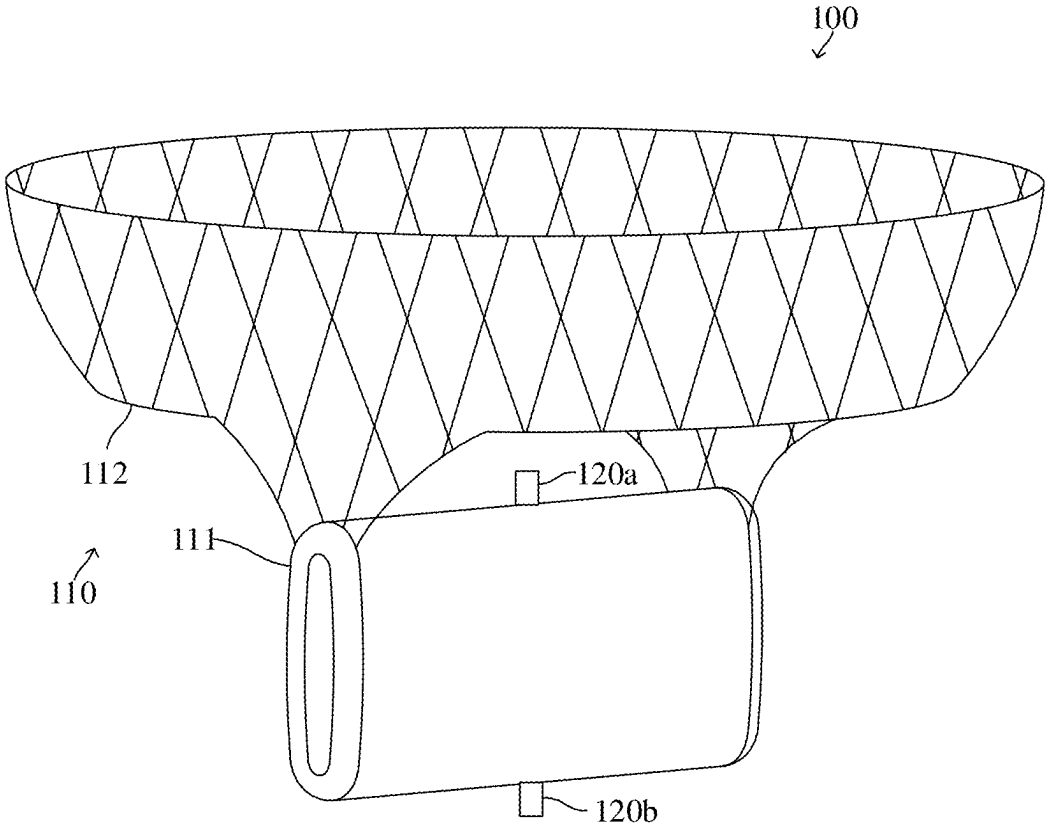


FIG. 17

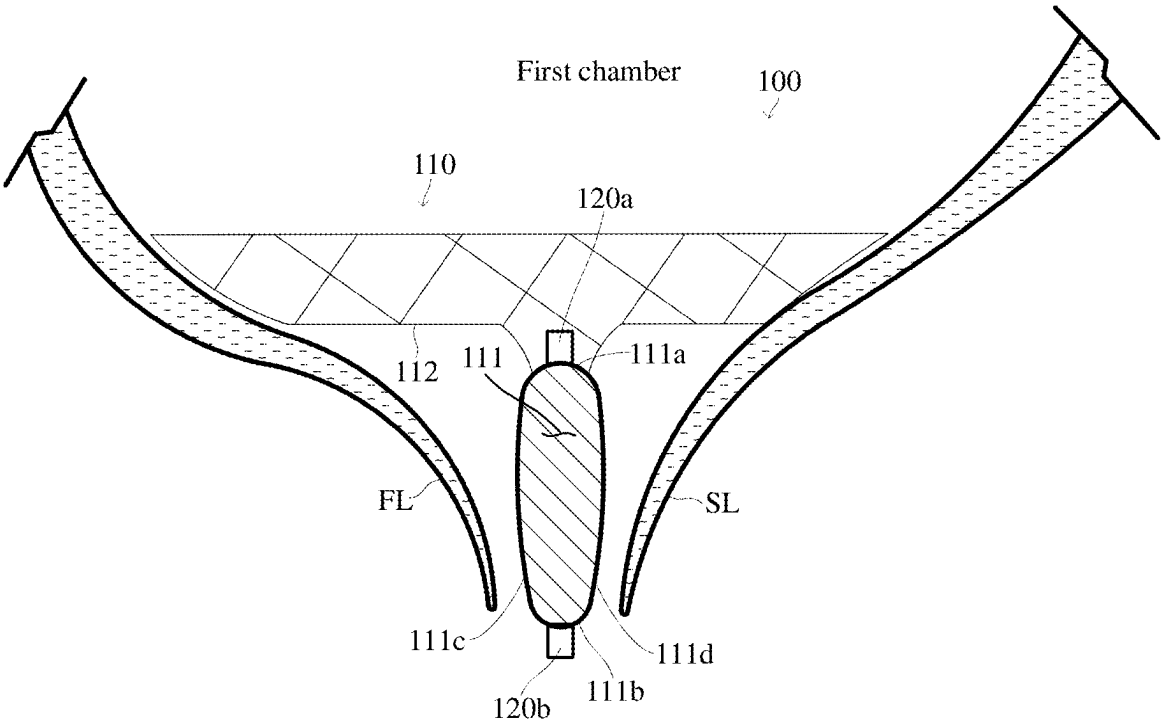

First chamber
100
110
120a
112
111
111a
FL
SL
111c
111d
120b
111b
Second chamber

FIG. 18

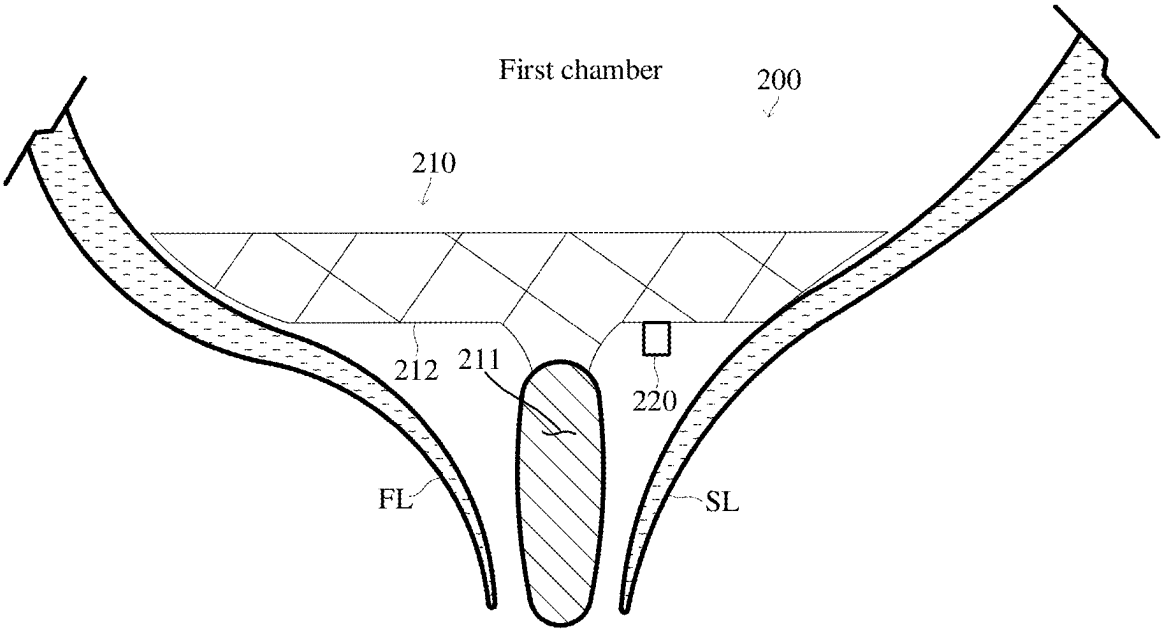


FIG. 19A

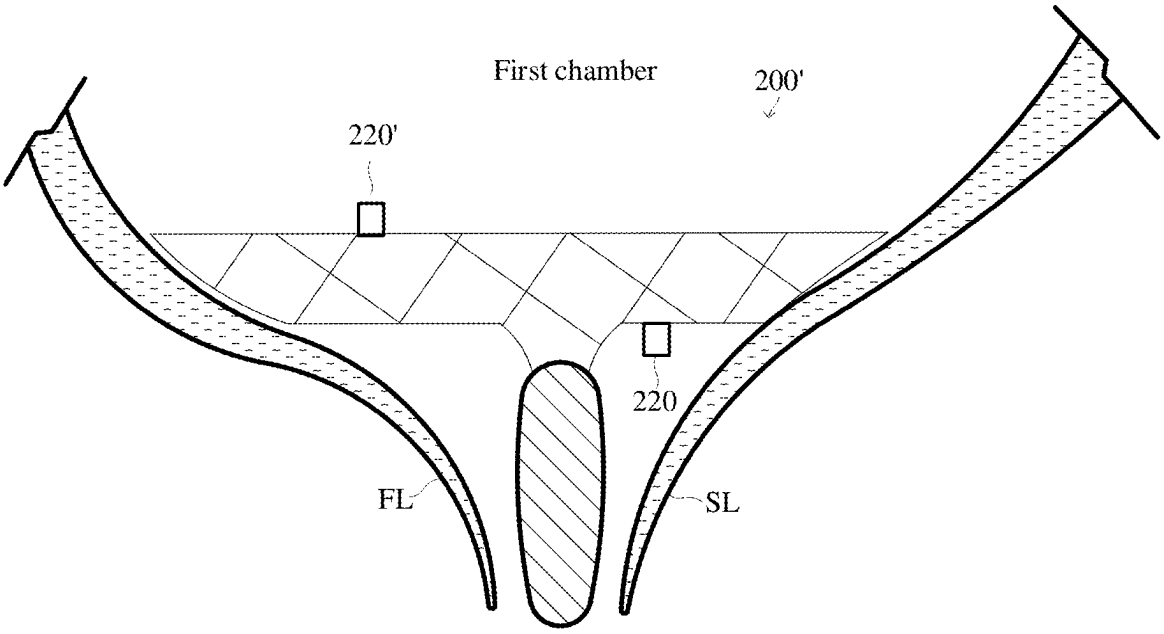


FIG. 19B

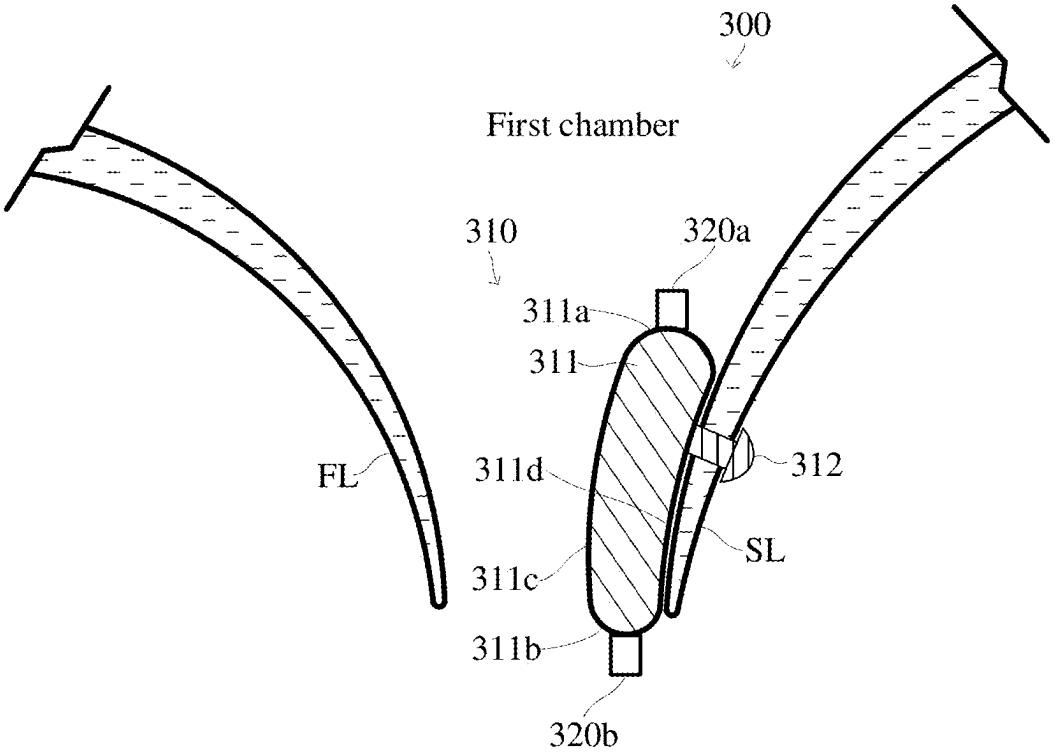

300
First chamber
310
320a
311a
311
FL
311d
312
SL
311c
311b
320b
Second chamber

FIG. 20

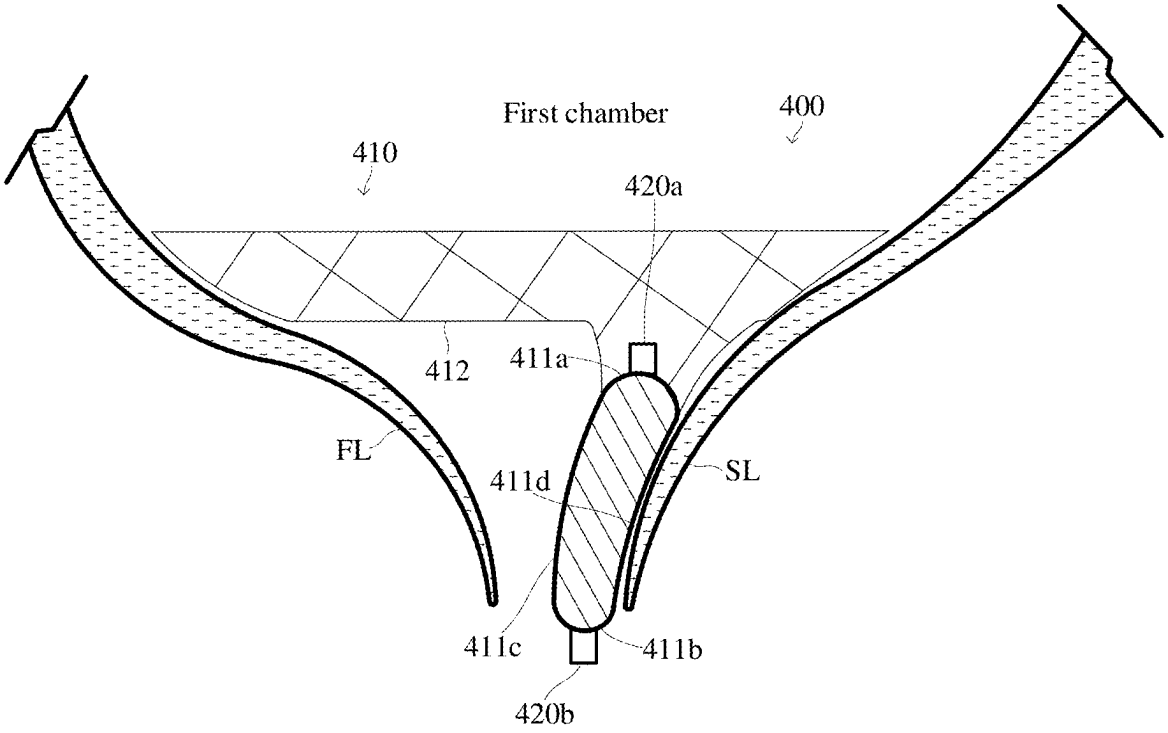
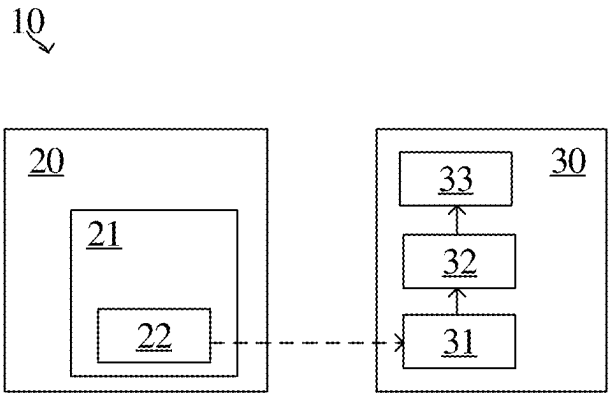

First chamber
400
410
420a
412
411a
FL
411d
SL
411c
411b
420b
Second chamber

FIG. 21


10
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21
22
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33
32
31

FIG. 22

MEDICAL DEVICE AND IMPLANT SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part application of International Application No. PCT/CN2023/126911, filed on Oct. 26, 2023, International Application No. PCT/CN2023/126908, filed on Oct. 26, 2023, and International Application No. PCT/CN2023/126897, filed on Oct. 26, 2023. International Application No. PCT/CN2023/126911 claims priority to Chinese Application No. 202211327911.6, filed on Oct. 27, 2022, and Chinese Application No. 202211328166.7, filed on Oct. 27, 2022. International Application No. PCT/CN2023/126908 claims priority to Chinese Application No. 202211327896.5, filed on Oct. 27, 2022. International Application No. PCT/CN2023/126897 claims priority to Chinese Application No. 202211330036.7, filed on Oct. 27, 2022. The entire contents of all the above applications are incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure relates to the field of medical apparatus and instruments technologies, and in particular, to a medical device and an implant system for repairing a heart valve of a patient.

BACKGROUND

[0003] A heart valve refers to a valve located between an atrium and a ventricle or a valve located between the ventricle and an artery. The valve plays a critical role in the heart' ceaseless blood circulation. After blood flows through, the valve closes to prevent blood regurgitation.

[0004] Various structural factors may affect proper closure of the heart valve, and thereby inducing the blood regurgitation. Taking mitral valve as an example, if the mitral valve fails to close properly, the blood may flow from the left ventricle to the left atrium through the mitral valve during systole, and thereby impairing a patient's health. A repair device for repairing the heart valve provided by related technologies has a structure similar to a clip. This medical device improves the condition of valve closure insufficiency by clipping onto a pair of leaflets of the valve.

[0005] However, such repair device has may defects. For instance, an effective area for the blood to flow through the valve is reduced due to such repair device, and so that another issue may be caused-stenosis. Additionally, as this repair device clips the pair of leaflets together, the pair of leaflets are prevented from naturally coaptating and separating during a cardiac cycle. As time goes on, this may cause problems to the structure and function of the pair of leaflets, then their associated tissues, and even the entire valve.

SUMMARY

[0006] In view of the above, in a first aspect, the present disclosure provides a medical device. The medical device provided by the present disclosure is used for improving the function of a patient's heart valve. This medical device includes a pad, the pad is configured to be capable of being positioned among a plurality of leaflets of the valve, to make the valve periodically open and close by cooperating with the leaflets.

[0007] In a second aspect, the present disclosure provides a medical device for repairing a heart valve of a patient. The medical device is adapted to be implanted in the patient's body to repair the valve. This medical device includes a pad and a control unit. The pad is configured to be located among the plurality of leaflets of the valve, to make the valve periodically open and close by cooperating with the plurality of leaflets. The pad includes an adjustment mechanism. The control unit is configured to control the adjustment mechanism to adjust a dimension of the pad.

[0008] In a third aspect, the present disclosure provides a cardiac implant adapted to be implanted in a patient's heart. The heart includes a first chamber, a second chamber and a valve. The valve is configured to periodically allow blood to flow from the first chamber to the second chamber. The cardiac implant includes a treatment device and at least one sensor. The treatment device is used for repairing the function of the valve to prevent the blood from flowing back from the second chamber to the first chamber, and the at least one sensor is attached to the treatment device and configured to sense a physiological information of the patient.

[0009] In a fourth aspect, the present disclosure further provides an implant system. The implant system includes the cardiac implant according to the above aspect and an external device. The at least one sensor includes a wireless transmission unit, and the external device includes a wireless reception unit configured to receive a pressure value information sent from the wireless transmission unit of the sensor.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] In order to more clearly illustrate technical solutions of embodiments of the present disclosure, the drawings to be used in the embodiments will be introduced briefly below.

[0011] It should be understood that, the drawings below merely show some embodiments of the present disclosure, but not all the embodiments.

[0012] It should be understood that, the same or similar reference numerals are used in the drawings for representing the same or similar elements.

[0013] It should be understood that, the drawings are merely illustrative, and dimensions and proportions of the elements in the drawings are not necessarily accurate.

[0014] FIG. **1** is a schematic structural diagram of a medical device according to an embodiment of the present disclosure.

[0015] FIG. **2** is a schematic structural diagram of a medical device according to another embodiment of the present disclosure.

[0016] FIG. **3**A and FIG. **3**B are schematic structural diagrams of a pad of the medical device of FIG. **2**.

[0017] FIG. **4** is an axonometric schematic structural diagram of the medical device in FIG. **2**.

[0018] FIG. **5** is a schematic structural diagram of a pad of a medical device according to another embodiment of the present disclosure.

[0019] FIG. **6** is a schematic structural diagram of a medical device according to yet another embodiment of the present disclosure.

[0020] FIG. **7** is a schematic structural diagram of a medical device according to still another embodiment of the present disclosure.

[0021] FIG. **8**A and FIG. **8**B are schematic structural diagrams of a pad of the medical device of FIG. **7**.

[0022] FIG. **9** is a schematic structural diagram of a medical device according to further another embodiment of the present disclosure.

[0023] FIG. **10** is a schematic structural diagram of a medical device according to yet a further embodiment of the present disclosure.

[0024] FIG. **11** is a schematic structural diagram of a medical device according to an embodiment of the present disclosure.

[0025] FIG. **12**A and FIG. **12**B are schematic structural diagrams illustrating a pad, a control system, a sensor, and the like of the medical device of FIG. **11**.

[0026] FIG. **13**A and FIG. **13**B are schematic structural diagrams of at least a portion of a pad of a medical device according to another embodiment of the present disclosure.

[0027] FIG. **14** is a schematic structural diagram of at least a portion of a medical device according to yet another embodiment of the present disclosure.

[0028] FIG. **15** is a schematic structural diagram of at least a portion of a medical device according to still another embodiment of the present disclosure.

[0029] FIG. **16** is a schematic structural diagram of at least a portion of a medical device according to further another embodiment of the present disclosure.

[0030] FIG. **17** is a schematic structural diagram of a cardiac implant according to an embodiment of the present disclosure.

[0031] FIG. **18** is a schematic structural diagram illustrating the cardiac implant of FIG. **17** located in a patient's heart.

[0032] FIG. **19**A is a schematic structural diagram illustrating a cardiac implant according to another embodiment of the present disclosure that is located in a patient's heart.

[0033] FIG. **19**B is a schematic structural diagram illustrating a cardiac implant according to yet another embodiment of the present disclosure that is located in a patient's heart.

[0034] FIG. **20** is a schematic structural diagram illustrating a cardiac implant according to still another embodiment of the present disclosure that is located in a patient's heart.

[0035] FIG. **21** is a schematic structural diagram illustrating a cardiac implant according to further another embodiment of the present disclosure that is located in a patient's heart.

[0036] FIG. **22** is a schematic structural diagram of an implant system according to an embodiment of the present disclosure.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0037] To make a person skilled in the art better understand technical solutions of the present disclosure, the technical solutions of implementations of the present disclosure will be described below with reference to the drawings. Apparently, the described implementations are merely some implementations of the present disclosure, rather than all the implementations.

[0038] It is considered that the repair device for repairing the valve that has a structure similar to a clip has many defects as mentioned above, the present disclosure provides a novel medical device for repairing a patient's valve. The medical device provided by the present disclosure includes a pad configured to be located among a plurality of leaflets of the valve, to make the valve periodically open and close by cooperating with the plurality of leaflets.

[0039] By the pad located among the plurality of leaflets, the medical device provided by the present disclosure is able to improve the closure condition of the valve, so that the valve is properly closed, and thus the regurgitation of blood is effectively prevented or reduced. Furthermore, the medical device provided by the present disclosure has less interference to blood flow, and therefore is able to reduce the possibility of stenosis. In addition, the medical device provided by the present disclosure has a minimal influence on the movement of the leaflets, so that fewer adverse effects on the structure and function of the leaflets are caused.

[0040] The valve involved in the present disclosure may be heart valves. In particular, the valve may be a mitral valve or tricuspid valve. When the valve is a mitral valve, the plurality of leaflets involved in the present disclosure may be the two leaflets of the mitral valve. When the valve is a tricuspid valve, the plurality of leaflets may be the three leaflets of the tricuspid valve. It should be understood that, the medical device provided by the present disclosure is not limited to application in mitral and tricuspid valves, but may also be applied to other valves.

[0041] The medical device provided by the present disclosure will be described below with reference to the drawings. It should be noted that, in FIG. **1** to FIG. **5** of the present disclosure, an arrow X is used for indicating a width direction of a pad, an arrow Y is used for indicating a thickness direction of the pad, and an arrow Z is used for indicating a height direction of the pad. FIG. **1** is a schematic structural diagram of a medical device **10** according to an embodiment of the present disclosure, and FIG. **1** illustrates a state that the medical device **10** is placed in a heart valve of a patient.

[0042] In FIG. **1** (and other figures of the present disclosure), the heart valve is located between a first chamber and a second chamber of the heart, to allow blood to flow from the first chamber to the second chamber while preventing flowing in a reverse direction. The heart valve includes a pair of leaflets FL, SL matching with each other.

[0043] In a normal condition, the leaflets FL, SL are able to naturally coaptate to close the valve and separate to open the valve during a cardiac cycle, so that the blood is allowed to flow from the first chamber to the second chamber while preventing flowing in a reverse direction. However, for a patient with valvular insufficiency, when the valve is required to close, the leaflets FL, SL fail to achieve proper coaptation. For example, a degree of coaptation is significantly reduced, and even there is a gap between the leaflets FL, SL. Therefore, this makes the blood flow from the second chamber back into the first chamber through the valve, and thus resulting regurgitation during systole.

[0044] The valve shown in FIG. **1** (as well as in other figures of the present disclosure) may be a mitral valve. Correspondingly, the first chamber is the left atrium, the second chamber is the left ventricle, and one of the leaflets FL, SL is the anterior leaflet while the other is the posterior leaflet. It should be understood that, the medical device provided in the present disclosure is not limited to application in the mitral valve, but may also be applied to other heart valves.

[0045] Referring to FIG. **1**, the medical device **10** includes a pad **11**. When the medical device **10** is implanted in a

patient's heart, the pad **11** is located between the leaflet FL and leaflet SL. The pad **11** has a pair of coaptation surfaces **111**, **112**. When the medical device **10** is implanted in the patient's heart, the pair of coaptation surfaces **111**, **112** respectively face the pair of leaflets FL, SL, namely the coaptation surface **111** faces the leaflet FL and the coaptation surface **112** faces the leaflet SL. With the changes of the cardiac cycle, each coaptation surface of the pair of coaptation surfaces **111**, **112** periodically coaptates and separates from the leaflet it faces. Specifically, when the valve closes, the coaptation surface **111** coaptates the leaflet FL and the coaptation surface **112** coaptates the leaflet SL to prevent the blood flowing from the second chamber back to the first chamber. When the valve opens, the leaflets FL, SL separate from coaptation surfaces **111**, **112** respectively to allow the blood to flow from the first chamber into the second chamber. In an example, a coaptation length between each coaptation surface and its corresponding leaflet may range from 6 mm to 12 mm. In an example, the coaptation surfaces **111**, **112** may be smooth transition curved surfaces to reduce resistance to the blood flow.

[0046] In this implementation, the valve is able to be opened and closed periodically by their own movement, and effective closure of the leaflets is increased through the coaptation of the pad and the leaflet during systole. Therefore, it not only able to allow the blood to automatically flow from the first chamber to the second chamber during diastole, but also reverse flow during systole caused by poor coaptation of the original two leaflets is effectively prevented.

[0047] Referring again to FIG. **1**, the medical device **10** may further include a support member **12**. When the medical device **10** is implanted in a patient's heart, the support member **12** is located in the first chamber and is connected to the pad **11**, so that the pad **11** is positioned between the pair of leaflets SL, FL. By placing the support member **12** in the first chamber, the pad **11** is able to be reliably positioned between the pair of leaflets FL, SL. In an example, the pad **11** may be rigidly connected to the support member **12** to consistently maintain the pad **11** in a proper position, avoiding changes in the position of the pad **11** due to the influence of blood flow or the leaflets FL, SL. If the pad **11** cannot be maintained in a proper position, it cannot be ensured that the pair of leaflets FL, SL will achieve good coaptation with the pair of coaptation surfaces **111**, **112** each time the valve closes.

[0048] The support member may be implemented in various ways, which are not specifically limited in the present disclosure.

[0049] As an example, referring again to FIG. **1**, the support member **12** may be annular in shape. When the medical device **10** is implanted in a patient's heart, the support member **12** may be placed at the annulus of the valve of the heart. In some embodiments, the support member **12** may have a mesh frame structure. During delivery, the support member **12** may firstly be folded to reduce its volume, to make the delivery process be easy. Once the support member **12** is delivered to a target position, it may be unfolded again.

[0050] It should be understood that, the implementation of the support member is not limited to the above, as long as it is able to position the pad between the pair of leaflets of the valve. For example, in some embodiments, the support member may also be semi-annular or partially annular. In some embodiments, the support member may be made of a flexible material, so that it is able to deform in accordance with systole and diastole of the first chamber, and thereby reducing adverse effects on physiological functions of the heart.

[0051] FIG. **2** is a schematic structural diagram of a medical device **20** according to another embodiment of the present disclosure, showing a state that the medical device **20** is placed at a heart valve of a patient.

[0052] Referring to FIG. **2**, the medical device **20** includes a pad **21**. In some embodiments, the pad **21** may be configured such that its thickness gradually increases toward a first chamber (that is, along the height direction, the pad has a gradually increasing cross-sectional area from its bottom end to its top end), thereby better matching with shapes of a pair of leaflets FL, SL, and thus the closure of the valve is more effectively achieved.

[0053] When the medical device **20** is implanted in the patient's heart, the pad **21** is located between the pair of leaflets FL, SL. The pad **21** has a pair of coaptation surfaces **211**, **212**. When the medical device **20** is implanted in the patient's heart, the pair of coaptation surfaces **211**, **212** respectively face the pair of leaflets FL, SL. As the pair of leaflets FL, SL move, each coaptation surface periodically coaptates and separates from the leaflet it faces.

[0054] The pair of coaptation surfaces **211**, **212** may both be inwardly concave surfaces, that is, concave surfaces, and the concave surfaces are recessed toward the interior of the pad **21**. Specifically, when the medical device **20** is implanted in the patient's heart, the coaptation surface **211** may be recessed in a direction away from the leaflet it faces (that is, the leaflet FL), and the coaptation surface **212** may be recessed in a direction away from the leaflet it faces (that is, the leaflet SL).

[0055] In this way, the pair of coaptation surfaces are able to better match with the leaflets they face respectively, so that the pair of coaptation surfaces better coaptate the leaflets they face respectively.

[0056] As an example, referring again to FIG. **2**, when the medical device **20** is implanted in the patient's heart, the coaptation surface **211** may be constructed to gradually extend toward a side where the leaflet FL it faces is located (that is, the left side in FIG. **2**) in a direction trending towards the first chamber. That is, along a height direction of the pad **21**, from the bottom end to the top end of the pad **21**, included angles between tangent lines of points on the coaptation surface **211** on the same longitudinal section and the height direction gradually increase. Similarly, the coaptation surface **212** may be constructed to gradually extend toward a side where the leaflet SL it faces is located (that is., the right side in FIG. **2**) in a direction trending towards the first chamber. That is, along the height direction of the pad **21**, from the bottom end to the top end of the pad **21**, included angles between tangent lines of points on the coaptation surface **212** on the same longitudinal section and the height direction gradually increase. The pair of coaptation surfaces **211**, **212** are smooth curved surfaces respectively. The pad **21** also includes a top surface **213** and a bottom surface, an end of the top surface **213** connected to the pair of coaptation surfaces **211**, **212** is the top end, and an end of the bottom surface connected to the pair of coaptation surfaces **211**, **212** is the bottom end.

[0057] In some cases, there may still be a small amount of blood flowing from the second chamber back into the first

chamber. By constructing the pair of coaptation surfaces to be concave in directions away from the leaflets they face respectively, and to gradually extend toward the sides where the leaflets they face are located in the direction trending towards the first chamber respectively, so that the flow direction of blood regurgitating from the second chamber to the first chamber is able to be changed, thereby the blood flow being guided to one side to prevent it from directly impacting the first chamber, and thus the direct "impact" of the regurgitation on the patient's atrium and pulmonary veins is reduced to reduce adverse effects on the cardiac function.

[0058] FIG. **3**A is a schematic structural diagram of the pad **21**. In FIG. **3**A, thick arrows are used for schematically indicating the changing trend of the flow direction of the blood flow that flows from the second chamber to the first chamber under the guidance of the pair of coaptation surfaces **211**, **212**.

[0059] Referring to FIG. **2** and FIG. **3**A, the coaptation surface **211** has a first edge portion **211***a* and a second edge portion **211***b* located at two opposite ends (a top end and a bottom end) thereof, respectively. When the medical device **20** is implanted in the patient's heart, the first edge portion **211***a* is closer to the first chamber than to the second edge portion **211***b*. Included angles between tangent planes at positions on the coaptation surface **211** and a tangent plane at the second edge portion **211***b* gradually increase as the positions on the coaptation surface **211** trends towards the first edge portion **211***a*. An included angle (acute angle) α**1** formed between a tangent plane at the first edge portion **211***a* and the tangent plane at the second edge portion **211***b* may range from greater than or equal to 10° to less than or equal to 45°. Preferably, the range of al may be from greater than or equal to 15° to less than or equal to 30°.

[0060] The coaptation surface **212** has a first edge portion **212***a* and a second edge portion **212***b* located at two opposite ends thereof, respectively. When the medical device **20** is implanted in the patient's heart, the first edge portion **212***a* is closer to the first chamber than to the second edge portion **212***b*. Included angles between tangent planes at positions on the coaptation surface **212** and a tangent plane at the second edge portion **212***b* gradually increase as the positions on the coaptation surface **212** approach the first edge portion **212***a*. That is, on the same longitudinal section, included angles between tangent lines of points on the coaptation surface **212** and the tangent line of the second edge portion **212***b* gradually increase as the points on the coaptation surface **212** trends towards the first edge portion **212***a*. An included angle (acute angle) α**2** formed between a tangent plane at the first edge portion **212***a* and the tangent plane at the second edge portion **212***b* ranges from greater than 45° to less than 90°. The included angle al and the included angle α**2** may be equal or unequal, which is not specifically limited in the present disclosure.

[0061] The greater the included angle between the tangent plane at the first edge portion and the tangent plane at the second edge portion, the greater the change in the flow direction of blood flow that flows from the second chamber to the first chamber caused by the coaptation surface. By setting the included angle between the two within the range of 45° to 90°, the blood flow that flows from the second chamber to the first chamber is effectively guided to one side while ensuring proper coaptation between the leaflets and the coaptation surfaces respectively.

[0062] It may be understood that, in other embodiments, if the device is used for a valve with three leaflets, the pad may have a third coaptation surface. At least a portion of the third coaptation surface periodically coaptates and separates from the it faces. Meanwhile, the third coaptation surface may also have any of the configurations of the first or second coaptation surfaces described in the above embodiments and achieve the same function.

[0063] Referring again to FIG. **2**, the pad **21** may also include a top surface **213** and a bottom surface, the top surface **213** and the bottom surface may be outwardly convex surfaces, that is, convex surfaces, and the convex surface protrudes toward the exterior of the pad **21**. Specifically, when the medical device **20** is implanted in the patient's heart, the top surface **213** of the pad **21** is located at an end of the pad **21** close to the first chamber, and the top surface **213** faces the first chamber and protrudes toward the first chamber. The bottom surface of the pad **21** is located at an end of the pad close to the second chamber, and the bottom surface faces the second chamber and protrudes toward the second chamber.

[0064] To better match with the pair of leaflets of the valve, the thickness of the pad may be constructed to gradually increase towards the first chamber, which may cause the blood to be more easily accumulated at the top of the pad. In the above implementation of the present disclosure, since the pad has a top surface that is convex (in the direction toward the first chamber), so that the accumulation of the blood at the top of the pad is effectively prevented or reduced.

[0065] In an example, referring again to FIG. **2**, when the medical device **20** is implanted in the patient's heart, the top surface **213** of the pad **21** may be constructed to trend towards the side where each of the pair of leaflets FL, SL is located while gradually extend toward the second chamber from its middle portion.

[0066] Specifically, as shown in FIG. **2**, the top surface **213** trends towards the side where the leaflet FL is located while (that is, the left side in FIG. **2**) gradually extending toward the second chamber or away from the support member **22** (that is, gradually extending downward in FIG. **2**) from its middle portion. Meanwhile, the top surface **213** approaches the side where the leaflet SL is located (that is, the right side in FIG. **2**) while gradually extending toward the second chamber or away from the support member **22** (that is, gradually extending downward in FIG. **2**) from its middle portion. In other words, the top surface **213** has a configuration that is higher in the middle and lower at both ends

[0067] FIG. **3**B is a schematic structural diagram of the pad **21**. In FIG. **3**B, thick arrows are used for schematically indicating the changing trend of the flow direction of blood flow that flows from the first chamber to the second chamber under the guidance of the top surface **213** of the pad **21**.

[0068] Referring to FIG. **2** and FIG. **3**B, the top surface **213** has edge portions **213***a*, **213***b* at two ends thereof in the thickness direction of the pad **21**, respectively. When the medical device **10** is implanted in the patient's heart, the edge portion **213***a* is closer to the leaflet FL (or closer to the coaptation surface **211**) than the edge portion **213***b*, and the edge portion **213***b* is closer to the leaflet SL (or closer to the coaptation surface **212**) than the edge portion **213***a*.

[0069] An included angle between a tangent plane at the middle portion **213***c* of the top surface **213** and a tangent

plane at the edge portion **213***a* is defined as β**1**, and an included angle between the tangent plane at the middle portion **213***c* and a tangent plane at the edge portion **213***b* is defined as β**2**. The included angles β**1** and β**2** may range from greater than or equal to 10° to less than or equal to 45°. In an example, the included angles β**1** and β**2** may range from greater than or equal to 15° to less than or equal to 30°. In an example, the top surface **213** may be a smooth transition curved surface to reduce resistance to blood flow.

[0070] The configuration of the top surface in FIG. **2** and FIG. **3**B is able to better guide the blood flow that flows from the first chamber to the second chamber, so that obstruction to the blood flow that flows from the first chamber to the second chamber is reduced.

[0071] FIG. **4** is an axonometric schematic structural diagram of the medical device **20**.

[0072] As shown in FIG. **4**, the support member **22** includes a main body portion **221** and a pair of connecting portions **222**. As an example, the main body portion **221** may be annular in shape, and is constructed such that is adapted to be mounted at the valve annulus. Certainly, in other examples, the main body portion **221** may be semi-annular or other shapes. The pair of connecting portions **222** extend respectively to two sides of the pad **21** in the width direction and are connected to the pad **21**.

[0073] The pair of leaflets are located on two sides of the pad in the thickness direction, and the first chamber and the second chamber are located on two sides of the pad in the height direction. As an example, the thickness direction, height direction and width direction of the pad are mutually perpendicular to each other. When the valve opens, most of the blood will flow along the height direction and passes through two sides of the pad in the thickness direction, and eventually flows into the second chamber. Since most of the blood flows through the two sides of the pad in the thickness direction, so that this configuration of the support member is able to reduce the obstruction to the blood flow caused by the portions of the support member connected to the pad to a greater extent, and thus the influence of the medical device on the patient's normal physiological functions is reduced.

[0074] It should be noted that, in the various embodiments of the present disclosure described above, any one of the leaflet FL and leaflet SL may be the "first leaflet" mentioned in other sections (for example, the Summary section). Correspondingly, the coaptation surface facing the "first leaflet" may be the "first coaptation surface". The other one of the leaflet FL and leaflet SL may be the "second leaflet" mentioned in other sections (for example, the Summary section). Correspondingly, the coaptation surface facing the "second leaflet" may be the "second coaptation surface".

[0075] FIG. **5** is a schematic structural diagram of a pad **31** of a medical device according to an embodiment of the present disclosure.

[0076] As shown in FIG. **5**, the pad **31** includes an expandable mesh frame **31***a* and a cover **31***b* covering the mesh frame **31***a*. The pair of coaptation surfaces **311**, **312** and the top surface **313** may be a portion of an outer surface of the cover **31***b*. In an example, the cover **31***b* may be made of a biocompatible material and has a smooth outer surface to avoid or reduce the wear of the leaflets or discomfort when matching with the leaflets. In another implementation, the cover **31***b* may be provided merely on the top end of the pad without covering on the coaptation surface. In this way, endothelialization of the coaptation surface is developed more quickly, so that the influence on the leaflet tissue when the leaflets come into contact with the coaptation surface is reduced.

[0077] The shape and size of the pad mainly depend on the mesh frame **31***a*. During delivery, the mesh frame **31***a* may be folded to reduce an overall size of the pad **31**, thereby facilitating the delivery process. After the pad **31** is delivered to a target position, the mesh frame **31***a* may be unfolded to make the pad **31** have an appropriate size and shape. Additionally, this configuration having the mesh frame **31***a* allows a doctor to adaptively adjust the shape and size of the pad **31** according to differences in different patients' valve, so that the pad **31** is able to better fit with the patient's valves. The cover **31***b* covering the outer side of the mesh frame **3** la provides the pad **31** with a smooth surface, which on one hand helps to prevent or reduce tissue overgrowth or blood adhesion on the pad **31**, and on the other hand enables the pad **31** to coaptate the leaflets tightly.

[0078] FIG. **6** is a schematic structural diagram of a medical device **40** according to an embodiment of the present disclosure, showing a state that the medical device **40** is placed at a patient's heart valves.

[0079] As shown in FIG. **6**, the medical device **40** includes a pad **41** having a first coaptation surface **411**. When the medical device **40** is implanted in the patient's heart, the pad **41** is located between a first leaflet (FL) and a second leaflet (SL) of the heart valves and moves with the second leaflet SL. The first coaptation surface **411** faces the first leaflet FL and periodically coaptates and separates from the first leaflet FL as the pad **41** moves with the second leaflet SL. In an example, when the first coaptation surface **411** coaptates with the first leaflet FL, a coaptation length between them may range from 6 mm to 12 mm.

[0080] Through the pad **41** locating between the pair of leaflets, the medical device **40** is able to improve the closure of the valve, so that the first leaflet FL coaptate the second leaflet SL properly, and thus the regurgitation of the blood is effectively prevented or reduced. Additionally, the medical device **40** has less interferes with blood flow, so that the possibility of stenosis is reduced. Furthermore, the medical device **40** does not affect or has less influence on the motion of the leaflet, so that no or less problems is caused to the function and structure of the leaflets. In other words, by using the medical device **40** provided by the present disclosure, there is no restriction or obstruction on the natural motion of the valve (closing, opening). Meanwhile, it is not associated with the valve's supporting structures, so that there are no adverse effects to be caused. That is, the physiological cyclic motion of each leaflet will not be disturbed or be less disturbed. As a result, the medical device **40** will cause less fewer problems to the structure and function of the leaflets. Moreover, the valve is able to cyclically open and close through their own natural motion, and during systole, sufficient closure of the leaflets is increased through the coaptation between the pad **41** and the leaflet. This not only allows the blood to flow from the first chamber to the second chamber during diastole, but also effectively prevents the regurgitation during systole that caused by the insufficient coaptation between the two leaflets.

[0081] The pad **41** may be attached to the second leaflet SL to move with the second leaflet SL. In other words, the pad **41** may be attached to the second leaflet SL in such a way that it follows the motion of the second leaflet SL and

becomes a portion of the second leaflet SL, so that the first coaptation surface **411** is able to periodically coaptate and separate from the first leaflet FL with the movement of the second leaflet SL.

[0082] As an exemplary implementation, referring again to FIG. **6**, the medical device **40** may also include a fixing member **42**. In an example, the fixing member **42** may be a pin **42**. When the medical device **40** is implanted in the patient's heart, the pin **42** may penetrate through the second leaflet SL to attach the pad **41** to the second leaflet SL, so that the pad **41** is able to move with the second leaflet SL.

[0083] The pin **42** may be integrally formed with the pad **41**, or the two may be separate members, which is not specifically limited in the embodiments of the present disclosure.

[0084] FIG. **7** is a schematic structural diagram of a medical device **50** according to still another embodiment of the present disclosure, showing a state that the medical device **50** is placed at a patient's heart valves.

[0085] As shown in FIG. **7**, the medical device **50** includes a pad **51** having a first coaptation surface **511**. In some embodiments, the pad **51** may be configured such that its thickness gradually increases towards the first chamber (that is, along the height direction, the pad has a gradually increasing larger cross-sectional area from the bottom end to the top end of the pad), so that the pad **51** better matches with the shapes of the first leaflet FL and the second leaflet SL, and thus the closure of the valve is improved.

[0086] When the medical device **50** is implanted in the patient's heart, the pad **51** is located between the first leaflet FL and the second leaflet SL and moves with the second leaflet SL. The first coaptation surface **511** faces the first leaflet FL and periodically coaptates and separates from the first leaflet FL as the pad **51** moves with the second leaflet SL.

[0087] The first coaptation surface **511** may be a recessed surface. More specifically, when the medical device **50** is implanted in the patient's heart, the first coaptation surface **511** may be recessed in a direction away from the first leaflet FL. This configuration allows the first coaptation surface **511** to better match with the first leaflet FL, so that better coaptation between the first coaptation surface **511** and the first leaflet FL is achieved.

[0088] Referring again to FIG. **7**, in a non-limiting example, when the medical device **50** is implanted in the patient's heart, the first coaptation surface **511** gradually extends toward the side where the first leaflet FL is located (that is, the left side in FIG. **7**) in the direction trending towards the first chamber.

[0089] In some cases, there may still be a small amount of blood flow from the second chamber back into the first chamber. The first coaptation surface **511** (away from the first leaflet FL) is concave and gradually extends toward the side where the first leaflet FL is located in the direction trending towards the first chamber, this configuration enables to increase the resistance of blood flow, so that the regurgitant is reduced, and the flow direction of the blood flow that flows from the second chamber to the first chamber is changed. Therefore, the blood flow is guided to one side, so that the blood flow is prevented from directly impacting the first chamber, and thus the adverse effects on the patient's cardiac function caused by the regurgitant that flows from the second chamber to the first chamber is reduced.

[0090] FIG. **8**A is a schematic structural diagram of a pad **51**. As shown in FIG. **8**A, the direction indicated by the thick arrow may represent the flow direction of blood that flows from the second chamber to the first chamber under the guidance of the first coaptation surface **511**.

[0091] As an exemplary implementation, referring to FIG. **7**, FIG. **8**A, and FIG. **8**B, the first coaptation surface **511** has a first edge portion **511***a* and a second edge portion **511***b* located at two opposite ends (the top end and the bottom end) thereof along the height direction, respectively. When the medical device **50** is implanted in a patient's heart, the first edge portion **511***a* is closer to the first chamber than the second edge portion **511***b*. The pad **51** also includes a top surface **512** and a bottom surface, an end where the top surface **512** is connected to the first coaptation surface **511** is the top end, and the end where the bottom surface is connected to the first coaptation surface **511** is the bottom end.

[0092] Included angles between tangent planes at positions on the first coaptation surface **511** and a tangent plane at the second edge portion **511***b* gradually increase as they approach the first edge portion **511***a*. An included angle (acute angle) α formed between a tangent plane at the first edge portion **511***a* and the tangent plane at the second edge portion **511***b* may range from greater than or equal to 10° to less than or equal to 45°. In an example, the included angle a may range from greater than or equal to 15° to less than or equal to 30°.

[0093] The greater the included angle a between the tangent plane at the first edge portion **511***a* and the tangent plane at the second edge portion **511***b*, the greater the flow direction of blood flow that flows from the second chamber to the first chamber changed by the first coaptation surface **511**. The included angle a of the two is set within this range, so that the blood flow that flows from the second chamber to the first chamber is able to be effectively guided to one side on the basis of ensuring the good coaptation of the first leaflet FL and the first coaptation surface **511**.

[0094] In an example, referring again to FIG. **7**, the pad **51** may also include a top surface **512**, and the top surface **512** may be a convex surface. When the medical device **50** is implanted in the patient's heart, the top surface **512** of the pad **51** is located at the end of the pad closer to the first chamber, and the top surface **512** faces the first chamber and protrudes (toward the first chamber), that is, the top surface **512** is a convex surface, and this convex surface protrudes toward the outside of the pad **51**.

[0095] To better match with the first leaflet FL and the second leaflet SL, the thickness of the pad **51** gradually increases towards the first chamber, which may lead to the accumulation of the blood at the top of the pad **51**. Since the pad **51** has a top surface **512** that protrudes (toward the first chamber), so that the accumulation of the blood at the top of the pad **51** is effectively prevented or reduced.

[0096] In a non-limiting example, referring again to FIG. **7**, when the medical device **50** is implanted in the patient's heart, the top surface **512** of the pad **51** approaches the second chamber while gradually extending toward the side where the first leaflet FL is located (that is, the left side in FIG. **7**). In other words, along the height direction of the pad **51**, from the bottom end to the top end of the pad **51**, the cross-sectional area of the pad **51** increases.

[0097] This configuration of the top surface **512** of the pad **51** is able to effectively prevent or reduce the accumulation

of the blood at the top of the pad **51**. Additionally, this configuration of the top surface **512** of the pad **51** is also able to reduce obstruction and interference to blood flow that flows from the first chamber to the second chamber caused by the pad **51**, and thereby better guiding blood flow to flow from the first chamber into the second chamber.

[0098] FIG. **8**B is a schematic structural diagram of the pad **51**. As shown in FIG. **8**B, the direction indicated by the thick arrow may represent the flow direction of blood flow that flows from the first chamber to the second chamber under the guidance of the top surface **512** of the pad **51**.

[0099] In an example, referring to FIGS. **7** and **8**B, the top surface **512** of the pad **51** includes a third edge portion **512***a* and a fourth edge portion **512***b* located at two opposite ends thereof in the thickness direction, respectively. When the medical device **50** is implanted in the patient's heart, the fourth edge portion **512***b* is closer to the second chamber than the third edge portion **512***a*.

[0100] Included angles between tangent planes of the top surface **512** and a tangent plane at the third edge portion **512***a* gradually increase as they approach the fourth edge portion **512***b*. An included angle β formed between the tangent plane at the third edge portion **512***a* and a tangent plane at the fourth edge portion **512***b* may range from greater than or equal to 10° to less than or equal to 45°. In an example, the included angle β may range from greater than or equal to 15° to less than or equal to 30°.

[0101] In this manner, the top surface **512** of the pad **51** is able to better guide the blood to flow from the first chamber to the second chamber, so that the obstruction caused by the pad **51** to the blood flow is reduced.

[0102] In a specific example, referring again to FIG. **7**, the pad **51** may also include a second coaptation surface **513**. The second coaptation surface **513** may be a recessed surface, that is, the second coaptation surface **513** may be a concave surface, this concave surface is recessed toward the interior of the pad **51**. More specifically, when the medical device **50** is implanted in the patient' s heart, the second coaptation surface **513** faces the second leaflet SL and is recessed away from the second leaflet SL. Additionally, when the medical device **50** is implanted, the second coaptation surface **513** approaches the first chamber while gradually extending toward the side where the second leaflet SL is located (that is, the right side in FIG. **7**). As the pad **51** moves with the second leaflet SL, the second coaptation surface **513** coaptates the second leaflet SL.

[0103] This configuration enables the second coaptation surface **513** of the pad **51** to better match with and fit with the second leaflet SL, so that the accumulation of the blood between the second coaptation surface **513** and the second leaflet SL is effectively prevented or reduced.

[0104] In a non-limiting example, referring again to FIG. **7**, the medical device **50** may also include a pin **52**. When the medical device **50** is implanted in the patient's heart, the pin **52** may penetrate through the second leaflet SL to attach the pad **51** to the second leaflet SL to make the pad **51** move with the second leaflet SL.

[0105] The pin **52** may be integrally formed with the pad **51**, or the two may be separate members, which is not specifically limited in the embodiments of the present disclosure.

[0106] There are various methods for attaching the pad to the second leaflet SL, which are not specifically limited in the present disclosure. One possible implementation is exemplarily described with reference to the accompanying drawings below.

[0107] FIG. **9** is a schematic structural diagram of a medical device **60** according to further another embodiment of the present disclosure. FIG. **9** illustrates a state that the medical device **60** is placed at heart valves of a patient. The medical device **60** is substantially the same as the medical device **20**, and for the sake of brevity, the similarities will not be described herein again.

[0108] Referring to FIG. **9**, the medical device **60** includes a pad **61** having a first coaptation surface **611**. When the medical device **60** is implanted in the patient's heart, the pad **61** is located between the first leaflet FL and the second leaflet SL and moves with the second leaflet SL. As the second leaflet SL moves, the first coaptation surface **611** periodically coaptates and separates from the first leaflet FL, so that the valve is cyclically closed and opened.

[0109] The medical device **60** also includes a clamping member **62**, and the clamping member **62** may be integrally formed with the pad **61**. Certainly, in other embodiments, the clamping member **62** may also be a member that is separate from the pad **61**. When the medical device **60** is implanted in the patient's heart, the clamping member **62** clamps the second leaflet SL to attach the pad **61** to the second leaflet SL, thereby enabling the pad **61** to move with the second leaflet SL

[0110] The present disclosure is not limited to attaching the pad to the second leaflet SL. Other implementations may also be used for positioning the pad between the first leaflet FL and the second leaflet SL and enabling the pad to move with the second leaflet SL.

[0111] FIG. **10** is a schematic structural diagram of a medical device **70** according to yet another embodiment of the present disclosure. FIG. **10** illustrates a state that the medical device **70** is placed at heart valves of a patient. The medical device **70** is substantially to the same as the medical device **20**, and for the sake of brevity, the similarities will not be described herein again.

[0112] Referring to FIG. **10**, the medical device **70** includes a pad **71** and a support member **72**. When the medical device **70** is implanted in the patient's heart, the support member **72** is located in the first chamber, and the pad **71** is connected to the support member **72** in a manner enabling it to move with the second leaflet SL, so that the pad **71** is positioned between the first leaflet FL and the second leaflet SL while following the motion of the second leaflet SL.

[0113] In a specific implementation, the pad **71** may be hinged with the support member **72** to make the pad **71** move with the second leaflet SL. In an example, as shown in FIG. **10**, the medical device **70** may also include a pivot shaft **73**, and the pad **71** is hinged with the support member **72** through the pivot shaft **73**. For instance, the pivot shaft **73** may be fixed to the pad **71** and is pivotally connected to the support member **72**, and thereby achieving the hinged connection between the pad **71** and the support member **72**. Alternatively, the pivot shaft **73** may be fixed to the support member **72** and pivotally connected to the pad **71**, and thereby achieving the hinged connection between the pad **71** and the support member **72**.

[0114] In another implementation, the pad **71** may be connected to the support member via a flexible member (or portion) to enable the pad **71** to move with the second leaflet SL.

[0115] By the support member **72** placed in the first chamber, the pad **71** is reliably positioned between the first leaflet FL and the second leaflet SL. The pad **71** is connected to the support member **72** in a manner that the pad **71** is allowed to move with the second leaflet SL, so that as the second leaflet SL moves, the pad **71** moves with the second leaflet SL, and thus the first coaptation surface coaptates and separates from the first leaflet FL periodically.

[0116] In an embodiment, the support member **72** may be annular to reduce the influence on the blood flow. Certainly, in other embodiments, the support member **72** maybe semi-annular or partially annular. In an implementation, the support member **72** may be constructed to be relatively soft, or more specifically have flexibility to adaptively deform with the systole and diastole of the first cardiac chamber, so that the adverse effects on the cardiac function are reduced.

[0117] There are various implementations of the support member **72**, which is not specifically limited in the present disclosure. In a non-limiting example, referring again to FIG. **10**, the support member **72** may be in a mesh frame shape that is able to be folded and unfolded. During implanting, the support member **72** may first be folded and then unfolded in the first chamber.

[0118] In some embodiments, the support member **72** may be placed at the valve annulus to enable the support member **72** to be reliably fixed.

[0119] In related art, a medical device for repairing heart valves includes a pad, and the pad may be delivered between leaflets of the valve of a patient by an operation. When the valve is closed, the pad is able to fill a gap between the leaflets, so that the closure of the valve is improved.

[0120] The condition of a patient is continuously developed. After the patient's condition develops to a certain extent, the pad that is initially implanted at the valve may no longer match with the patient's condition. For example, if the condition deteriorates, the pad will no longer be able to adequately fill the gap between the leaflets when the valve closes, so that the regurgitation will reappear. Conversely, if the condition improves (for example, if the ventricle begins to get smaller), the pad may reduce the effective orifice area through which the blood flows across the valve when it open, and thereby causing stenosis.

[0121] If the above situations occur, a repeat operation will be required to replace the pad initially implanted in the patient' body with one that matches with the patient's current condition. However, reoperation will increase economic burden on the patient and impair the patient's health.

[0122] In view of the above problems, the present disclosure provides a medical device. FIG. **11** is a schematic structural diagram of a medical device **10** according to an embodiment of the present disclosure. FIG. **11** illustrates a state that the medical device **10** is placed at heart valves of a patient. The medical device **10** (and other medical devices provided by the present disclosure) provided by the present disclosure is adapted to be implanted in a patient' body to repair the valve of the patient.

[0123] In FIG. **11** (and other drawings of the present disclosure), the heart valves are located between a first chamber and a second chamber to allow the blood to flow from the first chamber to the second chamber and preventing flow in the opposite direction. The heart valves include a pair of leaflets FL, SL matching with each other. For ease of description, the leaflet FL will be referred to as the first leaflet, and the leaflet SL will be referred to as the second leaflet hereinafter.

[0124] In a healthy heart, the pair of leaflets FL, SL are able to naturally coaptate and separate with the cardiac cycle to periodically close and open the valves, and thereby allowing the blood to flow from the first chamber to the second chamber while preventing flow in the opposite direction. However, for patients with valve insufficiency, when the valve is required to close, the pair of leaflets FL, SL fail to achieve proper coaptation, so that there is a gap between them, thereby the blood may flow through the valve from the second chamber back to the first chamber, and thus resulting in the regurgitation.

[0125] It should be noted that, the valve in FIG. **11** (and other drawings of the present disclosure) may be the mitral valve. Correspondingly, the first chamber may be the left atrium, the second chamber may be the left ventricle, and one of the pair of leaflets FL, SL may be the anterior leaflet while the other may be the posterior leaflet. It should be understood that, the medical device provided in the present disclosure is not limited to the application in the mitral valve but may also be applied to other heart valve, such as the tricuspid valve. When the medical device of the present disclosure is applied to the tricuspid valve, it may be located among the three leaflets of the tricuspid valve.

[0126] Referring to FIG. **11**, the medical device **10** includes a pad **11**. When the medical device **10** is implanted in a patient's heart, the pad **11** is located between the pair of leaflets FL, SL. The pad **11** is configured to cooperate with the pair of leaflets FL, SL to enable the valve to periodically open and close. Specifically, when the valve closes, the pad **11** may improve insufficient closure or fill the gap existing between the pair of leaflets FL, SL when closing, and thereby enabling the valve to close properly.

[0127] As an example, the pad **11** has a pair of coaptation surfaces **11***a*, **11***b*. When the medical device **10** is implanted in the patient's heart, the pair of coaptation surfaces **11***a*, **11***b* face the pair of leaflets FL and SL, respectively. For ease of description, the coaptation surface **11***a* will be referred to as the first coaptation surface, and the coaptation surface **11***b* will be referred to as the second coaptation surface hereinafter. With the changes of the cardiac cycle, each of the pair of coaptation surfaces **11***a*, **11***b* periodically coaptates and separates from the leaflet it faces, and thereby enabling the valve to open and close periodically. For example, a coaptation length between each coaptation surface and its corresponding leaflet may range from 6 mm to 12 mm.

[0128] Specifically, when the second chamber is in diastole, the pair of leaflets FL, SL move away from each other to form gaps between the pair of leaflets FL, SL and the pair of coaptation surfaces **11***a* and **11***b*, respectively. At this time, the valve opens to allow the blood to flow from the first chamber to the second chamber through these gaps. When the second chamber is in systole, the pair of leaflets FL, SL move toward each other to make the pair of leaflets FL, SL coaptate the pair of coaptation surfaces **11***a* and **11***b*, respectively. At this time, the valve closes to prevent the blood flow from the second chamber back to the first chamber.

[0129] It should be noted that, in the present disclosure, when the leaflet coaptate a coaptation surface, the leaflet and

the coaptation surface may contact and match with each other to prevent the blood from flowing through them.

[0130] It should be considered that the patient's condition is continuously developed, the pad may no longer match the patient's condition after being implanted for some time, and may fail to achieve the intended therapeutic effect and even cause adverse reactions. If this situation occurs, another operation would be required to replace the pad which is initially implanted in the patient's body with a pad matching with the patient's current condition. However, undergoing another operation would increase the patient's economic burden and have certain risks, and even impair the patient's health.

[0131] FIG. **12**A and FIG. **12**B are schematic structural diagrams illustrating the pad **11**, a control system **12**, a sensor **13**, and the like of the medical device **10**. As a portion of the medical device **10**, the pad **11**, the control system **12**, and the sensor **13** may all be implanted in the patient's body.

[0132] Referring to FIG. **12**A and FIG. **12**B, the medical device **10** may also include a control system **12**, the control system **12** may include a control unit **121**, and the pad **11** may include an adjustment mechanism. The control unit **121** is configured to control the adjustment mechanism to enable the adjustment mechanism to adjust a dimension of the pad **11**. In an example, the control unit **121** may be configured to control the adjustment mechanism to adjust the thickness of the pad **11**. The control unit **121** may include one or more controllers.

[0133] In this way, when the patient's condition changes, it is merely necessary to control the adjustment mechanism via the control unit to adjust the dimension of the pad, so that the pad matches with the patient's condition again. Since there is no requirement to perform operation again to replace the pad after the patient's condition develops, the use of this medical device is able to reduce the patient's economic burden and minimize the harm to their health.

[0134] In the present disclosure, the dimension of the pad that may be adjusted may be the dimensions of the pad at any dimensionality, but is not limited to its thickness. For example, in some embodiments, the adjustment mechanism may adjust one or more of the thickness, height, or width of the pad under the control of the control unit.

[0135] The thickness of the pad may refer to its dimension in the direction from one coaptation surface to the other. In other words, the pair of coaptation surfaces may be located on two sides of the pad along the thickness direction of the pad, respectively. That is, when the pad is implanted at the patient's valves, the pair of leaflets are located on two sides of the pad along the thickness direction of the pad.

[0136] The height of the pad may refer to a dimension of the pad in a direction from the first chamber to the second chamber when the pad is installed at the valve. The width of the pad may refer to a dimension of the pad in a direction perpendicular to the height and thickness directions.

[0137] For ease of understanding, in the drawings of the present disclosure, an arrow X is used for indicating a thickness direction of the pad, an arrow Y is used for indicating a width direction of the pad, and an arrow Z is used for indicating a height direction of the pad

[0138] There are various methods for adjusting the thickness of the pad, which are not specifically limited in the present disclosure.

[0139] As an example, referring to FIG. **11** to FIG. **12**B, the pad **11** includes a pair of main body members **111**, **112**. The main body members **111**, **112** are stacked in the thickness direction of the pad **11**. Each main body member has a free end and a connected end opposite to each other, that is, the main body member **111** has a free end **111***a* and a connected end **111***b*, and the main body member **112** has a free end **112***a* and a connected end **112***b*. The connected ends **111***b*, **112***b* of the main body members **111**, **112** are pivotally connected. The adjustment mechanism is configured to adjust an opening degree between the main body members **111**, **112** under the control of the control unit **121** to adjust the thickness of the pad **11**.

[0140] The opening degree between the main body members **111**, **112** may be defined by an included angle (acute angle) formed therebetween. In FIG. **12**A, the included angle $\alpha 1$ between the main body members **111**, **112** is less, so that the opening degree between the main body members **111**, **112** is less, and the thickness of the pad **11** is also less. In FIG. **12**B, the included angle α_2 between the main body members **111**, **112** is greater, so that the opening degree between the main body members **111**, **112** is greater, and the thickness of the pad **11** is also greater.

[0141] In this manner, the adjustment mechanism is able to regulate the thickness of the pad **11** under the control of the control unit. This implementation has many advantages, such as it is relatively simple to implement, and has a compact structure and high reliability.

[0142] It may be understood that, in other examples, the thickness of the pad **11** may also be adjusted in other manners. For instance, in some embodiments, the pad **11** may include a pair of plates stacked in the thickness direction, and the adjustment mechanism may adjust the thickness of the pad by adjusting a space between the plates.

[0143] There are various implementations of the adjustment mechanism, which are not specifically limited in the present disclosure.

[0144] As an example, the adjustment mechanism may include a driving member **113** and a sliding block **114**. The sliding block **114** is slidably disposed between the main body members **111**,**112** and abuts against the main body members **111**,**112**. The driving member **113** is configured to adjust the opening degree between the main body members **111**, **112** by driving the sliding block **114** to slide. Specifically, the adjustment mechanism is configured (under control of the control unit **121**) to: increase the opening degree between the main body members **111**, **112** by driving the sliding block **114** to move toward the connected ends **111***b*, **112***b* of the main body members **111**, **112**; or decrease the opening degree between the main body members **111**, **112** by driving the sliding block **114** to move toward the free ends **111***a*, **112***a* of the main body members **111**, **112**.

[0145] In this manner, the adjustment mechanism is able to adjust the opening degree between the pair of main body members **111**, **112** under the control of the control unit, and thereby adjusting the thickness of the pad **11**. This implementation has many advantages, such as it is relatively simple to implement, and has a compact structure and high reliability.

[0146] It may be understood that, in other examples, the adjustment mechanism may be implemented in other manners. For instance, in some embodiments, the adjustment mechanism may include a cam disposed between the pair of main body members, and the driving member may adjust the opening degree between the pair of main body members by driving the cam to rotate.

[0147] The sliding block may be driven in various ways, which are not specifically limited in the present disclosure.

[0148] As an example, referring to FIG. **12**A and FIG. **12**B, the driving member **113** may be a motor **113**. The adjustment mechanism may also include a pair of meshing bevel gears **115**, **116** and a leadscrew **117**, and the leadscrew **117** passes through a threaded hole provided in the sliding block **114**. The bevel gear **115** is mounted on an output shaft of the electric motor **113**, and the bevel gear **116** is mounted on the leadscrew **117**.

[0149] When the motor **113** rotates under the control of the control unit **121**, the driving force is transmitted through the bevel gears **115**, **116** to the leadscrew **117** to make the leadscrew **117** rotate. As the leadscrew **117** rotates, it drives the sliding block **114** to slide between the main body members **111**, **112**, so that the opening degree between the main body members **111**, **112** is adjusted, and thus the thickness of the pad **11** is adjusted.

[0150] In this manner, the sliding block is driven to slide between the pair of main body members **111**, **112**, so that the opening degree of the main body members **111**, **112** is adjusted, and thus the thickness of the pad **11** is adjusted. This implementation has many advantages, such as it is relatively simple to implement, and has a compact structure and high reliability.

[0151] It may be understood that, in other embodiments, the sliding block may also be driven in other manners. For example, in some embodiments, the sliding block may be a magnetic member, and the driving member may be an electromagnetic member, so that the sliding block is driven to slide by an electromagnetic force.

[0152] In an example, referring to FIG. **12**A and FIG. **12**B, the main body member **111** is provided with an accommodating groove **111***c*, the motor **113** is accommodated in the accommodating groove **111***c* to avoid occupying an additional space, which is convenient for reducing the overall size of the pad **11**. In an example, the main body member **111** also includes an elongated guiding slot **111***d*, a portion of the sliding block **114** extends into the guiding slot **111***d*, so that the guiding slot **111***d* is able to guide the sliding block **114** to slide along a preset trajectory. In an example, the main body member **111** includes a boss **111***e*, and the boss **111***e* has a through hole for the leadscrew **117** to pass through to provide support for the leadscrew **117**. In an example, the leadscrew **117** is provided with a shoulder **117***a*, and the shoulder **117***a* is located on a side of the boss **111***e* away from the sliding block **114** and abuts against the boss **111***e* to limit the leadscrew **117**.

[0153] As a possible implementation, referring to FIG. **12**A and FIG. **12**B, the pad **11** may include a cover **118**, and the cover **118** partially or completely covers the pair of main body members **111**, **112**. The cover **118** may define an external surface of the pad **11**. The pair of coaptation surfaces **11***a*, **11***b* of the pad **11** are provided by the cover **118**. In other words, the pair of coaptation surfaces **11***a*, **11***b* are a portion of the outer surface of the cover **118**. In some embodiments, the cover **118** may be made of a material with superior biocompatibility and having a smooth outer surface, and thereby reducing the adverse effect of the pad **11** on the health of the patient.

[0154] The control unit **121** may automatically control the adjustment mechanism to adjust the dimension of the pad according to the patient's condition, or may be operated in response to an instruction from a doctor or the patient to control the adjustment mechanism to adjust the dimension of the pad. This is not limited in the present disclosure.

[0155] As an example, referring to FIG. **12**A and FIG. **12**B, the control system **12** may also include a communication unit **122**. The communication unit **122** (for example, a communication interface or a signal transceiver) is configured to establish communication connection with a control device (for example, a controller) located outside the patient's body in a wireless manner. For example, the communication unit **122** may, but is not limited to, communicate with the external control device through the following manners: Bluetooth, cellular network, Wi-Fi, electromagnetic field, radio frequency communication, or ultrasonic communication, or the like.

[0156] The doctor (or the patient) may operate the control device to send a control instruction to the communication unit **122**. The communication unit **122** is configured to receive this control instruction and transmit it to the control unit **121**. Upon receiving the control instruction, the control unit **121** is configured to control the adjustment mechanism to adjust the dimensions of the pad **11** based on the control instruction.

[0157] After the medical device of the present disclosure is implanted, the patient may perform periodical follow-up examinations to confirm the change of the condition. When it is detected that the pad's dimension no longer matches with the patient's condition, the doctor may send a control instruction to the communication unit of the medical device implanted in the patient's body by the external control device. Upon receiving the control instruction, the control unit may control the adjustment mechanism to appropriately adjust the pad's dimension according to the control instruction, so that the pad matches with the patient's condition again.

[0158] As another example, referring to FIG. **12**A and FIG. **12**B, the medical device **10** may also include a sensor **13**, and the senor **13** is in communication connection with the control unit **121**. The sensor **13** is configured to sense the patient's physiological information and transmit the sensed physiological information to the control unit **121**, so that the control unit **121** controls the adjustment mechanism to adjust the dimension of the pad **11** based on the physiological information.

[0159] Illustratively, the physiological information may include, but is not limited to, one or more type of: blood pressure information, blood flow velocity information, blood pH information, blood temperature information, blood oxygen level information, electrocardiographic information, heart sound data, cardiac acceleration information, or cardiac contractility information in the patient's heart. Correspondingly, the sensor **13** in the present disclosure may be configured to sense one or more type of the aforementioned information.

[0160] Since there is the sensor **13** for sensing the physiological information that reflects the condition of the patient, the control unit **121** is able to control the adjustment mechanism to adjust the dimension of the pad **11** according to the physiological information, so that the pad **11** is able to always match with the condition of the patient. The medical provided by this implementation not only reduces the need for operation while improving the therapeutic effect, but also reduces the number of follow-up examinations of the patient after implantation, so that the economic burden and time cost of the patient is reduced.

[0161] It may be understood that, in some embodiments, the medical device provided by the present disclosure may merely include one of the communication unit **122** and the sensor **13**, or may include both the communication unit **122** and the sensor **13**, which is not specifically limited in the present disclosure.

[0162] There are a plurality of implementations of the sensor **13**, which is not specifically limited in the present disclosure.

[0163] As an example, referring to FIG. **11**, the sensor **13** may include a hemodynamic sensor, for example, a pressure sensor or an accelerometer. The sensor **13** may be attached to the outer surface of the pad **11** to sense physiological information reflecting a blood flow state at the valve. In other words, the physiological information sensed by the sensor **13** is able to reflect the blood flow state at the valve, that is, it is able to reflect whether there is regurgitation or stenosis. Therefore, the control unit **121** is able to adjust the dimension of the pad **11** appropriately based on the physiological information, so that the dimension of the pad **11** better matches with the patient's current condition.

[0164] It should be noted that, in other examples, the sensor **13** is attached to the pad **11**, but is located in the first chamber or the second chamber to monitor the hemodynamic information of the chamber.

[0165] It should be noted that, in other examples, the sensor **13** may not be attached to the pad **11**. For instance, in some implementations, the sensor **13** may be mounted on the leaflets. Alternatively, in some embodiments, the sensor **13** may be mounted on other members of the medical device, such as the support member **14**.

[0166] Furthermore, it should also be noted that, in some embodiments, the medical device provided in the present disclosure may include multiple sensors **13** which may be arranged at different positions-for example, one in the first chamber and another in the second chamber, so that the patient's condition is more accurately determined. Alternatively, a single sensor **13** may has two or more sensing elements to detect hemodynamic information from different chambers or different regions in a same chamber.

[0167] In an alternative implementation, the communication unit **122** may be configured to send the physiological information to an external device and receive a control instruction generated by the external device based on the physiological information. The control unit **121** may be configured to control the adjustment mechanism to adjust the dimension of the pad **11** in accordance with the control instruction. In this way, the complexity and power consumption of the medical device **10** is reduced.

[0168] To further reduce the energy consumption, in an example (as shown in FIG. **12**A and FIG. **12**B), the control system **12** may also include a wake-up unit **123** (for example, a controller for waking up). The wake-up unit **123** is configured to wake up one or more of the control unit **121**, the communication unit **122** and the sensor **13** based on a preset schedule.

[0169] Considering that the patient's condition generally develops slowly, so it is not necessary to frequently adjust the dimension of the pad **11**. In this implementation, the control unit **121**, the sensor **13**, the communication unit **122** and the like may be in a dormant state most of the time. After reaching a preset time point, the wake-up unit **123** may wake up one or more of them. In this way, the energy consumption may be effectively reduced, so that a purpose of power-saving is achieved.

[0170] As an example, the preset schedule may include a plurality of cycles, each cycle includes a sleep phase and a wake-up phase. During the sleep phase, all energy-consuming units except the wake-up unit **123** may be in a dormant state to reduce the power consumption. After the wake-up phase begins, the wake-up unit **123** may wake up some or all of the energy-consuming units.

[0171] For instance, one sleep phase may last from **6** months to **12** months, and one wake-up phase may last from **3** days to **7** days. The duration and start time of each phase may be set according to a requirement. The doctor may set the preset schedule to match with the follow-up examination plan of the patient, that is, the preset schedule is set so that the medical device **10** is just in the wake-up phase when the patient needs the follow-up examination. In this way, after the doctor checks the patient's condition, a control instruction is sent to the communication unit **122** through an external control device to adjust the dimension of the pad **11** to match with the condition of the patient after the follow-up examination.

[0172] In an alternative implementation, the wake-up unit **123** is also configured to wake up the control unit **121** in response to physiological information meeting a preset condition. For example, if the physiological information includes a blood pressure, the preset condition may be that the blood pressure is greater than or less than a preset threshold.

[0173] Referring again to FIG. **12**A and FIG. **12**B, the control system **12** may also include an energy supply unit **124**, and the energy supply unit **124** is configured to supply energy to one or more of the control unit **121**, the communication unit **122**, the wake-up unit **123**, and sensor **13**.

[0174] The energy supply unit **124** may be implemented in various ways, which is not specifically limited in the present disclosure. For instance, in some embodiments, the energy supply unit **124** may be a battery. In other embodiments, the energy supply unit **124** may be an induction coil, so that the doctor or the patient may recharge it via an external device. Alternatively, in some embodiments, the energy supply unit **124** may be an ultrasonic transducer, so that ultrasound waves transmitted by an external device may be converted into electrical energy. In some embodiments, the energy supply unit **124** may also be a device that converts kinetic energy into electrical energy.

[0175] To simplify the structure, in some implementations, the control system **12** may be partially or completely located inside the pad **11**. Certainly, in some embodiments, the control system **12** may be entirely located outside the pad **11**. This is not specifically limited in the present disclosure.

[0176] There are various methods for positioning the pad **11** between a pair of leaflets, which are not specifically limited in the present disclosure.

[0177] As an exemplary embodiment, with reference to FIG. **11**, the medical device **10** may also include a support member **14**. When the medical device **10** is implanted in a patient's heart, the support member **14** is located in the first chamber and is connected to the pad **11**, so that the pad **11** is positioned between the pair of leaflets (SL, FL). By the support member **14** located in the first chamber, the pad **11** is reliably positioned between the pair of leaflets FL, SL. In an example, the pad **11** may be rigidly connected to the

support member **14** to hold the pad **11** in a proper position all the time, so that the position of the pad **11** is prevented from moving due to the influence of the blood flow or the leaflets FL, SL. If the pad **11** cannot be held in the proper position, it cannot be ensured that the pair of leaflets FL, SL will properly coaptate the pair of coaptation surfaces **11***a*, **11***b* of the pad **11** respectively each time the valve closes.

[0178] The support member **14** may be implemented in various configurations, which are not specifically limited in the present disclosure.

[0179] As an example, referring to FIG. **11**, the support member **14** may be annular. When the medical device **10** is implanted in the patient's heart, the support member **14** may be placed at the valve annulus of the heart. In some embodiments, the support member **14** may have a mesh frame structure. During delivery, the support member **14** may be folded to reduce its volume. After reaching a target position, the support member **14** may be unfolded.

[0180] It may be understood that, the implementation of the support member **14** is not limited to the above examples, as long as it is able to position the pad between the pair of leaflets of the valve. For instance, in some embodiments, the support member **14** may be semi-annular.

[0181] The sensor **13** is disposed on the coaptation surface of the pad along the thickness direction of the pad, and in the height direction of the pad, the sensor **13** is configured to be closer to the first chamber than to the second chamber. When the medical device **10** includes the support member **14**, the sensor **13** is closer to an end of the pad connected to the support member **14** than an end of the pad away from the support member **14**, or the sensor **13** is located at the end of the pad connected to the support member **14**. In other embodiments, the medical device **10** may not include the support member **14**, and at this time, the sensor **13** may be disposed at an end of the pad closer to the first chamber. For example, the sensor **13** may be placed at the top end of the pad as shown in FIG. **7**. When the pair of leaflets match with the pad, the sensor **13** is located in a space formed by the leaflets, the pad and a wall of the left atrium for sensing the pressure of the left atrium. The sensor **13** is disposed at the position which is close to the area where the leaflet coaptates the pad to improve the accuracy and comparability of the sensing data, and meanwhile is not affected by the coaptation of the leaflet and the pad **11** to avoid the accuracy of the sensed data being affected due to the sensor **13** being covered by the leaflet. In an implementation, a side of the sensor **13** is connected to the coaptation surface of the pad **11**, and the sensing surface of the sensor faces the first chamber or the support member to further avoid the influence of the leaflet on the sensor and improve the sensing accuracy.

[0182] During ventricular systole and diastole, a pressure of the left atrium is able to be directly used for determining the regurgitation and stenosis at the heart valves, so that the adjustment mechanism may adjust the thickness of the pad based on the change of the pressure of the left atrium. For example, during the ventricular systole period, a an abnormally high value of the pressure of the left atrium (for example, greater than a preset value) indicates that there is the regurgitation, at this time, the valve is required to be closed more tightly, so that the thickness of the pad is required to be adjusted by the adjustment mechanism to make the pad become greater. Conversely, during ventricular diastole period, an abnormally high value of the left atrium indicates that there is the stenosis, and in this case, the thickness of the pad is required to be adjusted by adjustment mechanism to make the pad become less, so that the stenosis is reduced or eliminated. If the value of the pressure of the left atrium is not abnormal, the adjustment mechanism does not need to adjust the thickness of the pad. Specifically, when the value of the pressure of the left atrium is abnormally increased, the control unit may notify the doctor this phenomenon and let the doctor to perform corresponding treatment (for example, by using the control unit control the adjustment mechanism to adjust), or it may be automatically adjusted by the control unit.

[0183] It should be understood that, although the adjustment mechanism in the above embodiments is used for adjusting the thickness of the pad **11**, however, in other embodiments, the adjustment mechanism may be used for adjusting dimensions in other dimensionalities of the pad **11**. In the following, an alternative implementation is provided.

[0184] FIG. **13**A and FIG. **13**B are schematic structural diagrams showing at least a portion of a pad **21** according to another embodiment.

[0185] Referring to FIG. **13**A and FIG. **13**B, the pad **21** includes a pair of shells **211**, **212**. An end of the shell **212** is sleeved on an end of the shell **211**, and the two cooperatively defines an internal space **21***a*. The adjustment mechanism is configured to adjust an overlap degree between the pair of shells **211**, **212** under control of a control unit (for example, a controller), and thereby adjusting a width of the pad **21**.

[0186] When the pad **21** is in a state shown in FIG. **13**A, the overlap degree dl of the pair of shells **211**, **212** is less, and a width w**1** of the pad **21** is greater. When the pad **21** is in a state shown in FIG. **13**B, the overlap degree d**2** of the pair of shells **211**, **212** is greater, and the width w**2** of the pad **21** is less.

[0187] In this manner, the adjustment mechanism is able to adjust the width of the pad under the control of the control unit. This implementation has many advantages, such as such as it is relatively simple to implement, and has a compact structure and high reliability.

[0188] In some embodiments, the pad **21** may also include an expandable and contractible membrane layer (not shown in the figures) covering the pair of shells **211**, **212**. The membrane layer may have a smooth outer surface to prevent or reduce proliferation of epidermal cells or other tissues on the exterior of the pad **21**.

[0189] There are various manners to adjust the overlap degree of the pair of shells **211**, **212**, which are not specifically limited in the present disclosure.

[0190] As an example, referring to FIG. **13**A and FIG. **13**B, the adjustment mechanism may include a motor **213**, a pair of meshing gears **214**, **215**, a shaft **216** supporting the gear **215** and a rack **217** meshing with the gear **215**. The gear **214** is mounted on an output shaft of the motor **213**, the shaft **216** is fixed to the shell **211**, and an end of the rack **217** is fixed to the shell **212**. The motor **213** is able to rotate under control of the control unit to drive the rack **217** to move, and thereby changing the overlap degree of the pair of shells **211**, **212**.

[0191] It may be understood that, the manner of cooperation between the pad and the pair of leaflets is not limited to the above implementation. In the following, an alternative implementation is provided.

[0192] FIG. **14** is a schematic structural diagram showing at least a portion of a medical device **30** according to yet

another embodiment of the present disclosure. FIG. **14** illustrates a state that the medical device **30** is placed at a valve of a patient.

[0193] The medical device **30** has many same or similar elements with the medical device **10**. For purpose of conciseness, the related descriptions are appropriately omitted. It may be understood that, on the premise that no contradiction occurs, elements of the medical device **10** and the medical device **30** may be combined with each other.

[0194] Referring to FIG. **14**, the medical device **30** includes a pad **31** having a first coaptation surface **31***a* and a second coaptation surface **31***b*. When the medical device **30** is implanted at the patient's heart valves, the pad **31** is placed between the pair of leaflets FL, SL. The pad **31** is configured to follow the movement of the second leaflet SL, the second coaptation surface **31***b* is configured to face and maintain coaptating the second leaflet SL, and the first coaptation surface **31***a* is configured to face the first leaflet FL and periodically coaptate and separate from the first leaflet FL with the pad **31** following the movement of the second leaflet SL. In other words, during the changes of the cardiac cycle, the second coaptation surface **11***b* maintains constantly coaptating the second leaflet SL, and the first coaptation surface **11***a* periodically coaptates and separates from the first leaflet FL.

[0195] There are various ways to position the pad between the pair of leaflets to make the pad **31** move with the second leaflet, which is not specifically limited in the present disclosure. Several possible implementations are described below.

[0196] As an example, referring again to FIG. **14**, the medical device **30** may also include a support member **34**. When the medical device **30** is implanted in the patient's heart, the support member **34** is located in the first chamber, and the pad **31** is connected to the support member **34** in a manner allowing it to follow the movement of the second leaflet SL. For instance, the pad **31** may be hinged with the support member **34** to enable the pad **31** to follow the movement of the second leaflet SL. Alternatively, the pad **31** may be connected to the support member via a flexible member (or portion) to make the pad **31** move with the second leaflet SL.

[0197] Through the support member placed in the first chamber, the pad is able be reliably positioned between the first and second leaflets. The pad is connected to the support member in a manner enabling it to follow the movement of the second leaflet to ensure that as the second leaflet moves, the pad moves with the second leaflet, so that the first coaptation surface periodically coaptates and separates from the first leaflet.

[0198] FIG. **15** is a schematic structural diagram showing at least a portion of a medical device **40** according to still another embodiment of the present disclosure. FIG. **15** illustrates a state that the medical device **40** is implanted at a heart valve of a patient.

[0199] The medical device **40** has many same or similar elements with the medical devices **10**, **30**. For the purpose of conciseness, related descriptions are appropriately omitted. It may be understood that, on the premise that no contradiction occurs, elements of the medical device **40** and the medical device **10**, **30** may be combined with each other.

[0200] As another embodiment shown in FIG. **15**, the medical device **40** may include not only a pad **41** but also a pin **45**. When the medical device **40** is implanted in the patient's heart, the pip **45** penetrates through the second leaflet SL to attach the pad **41** to the second leaflet SL, and thereby locating the pad **41** between the pair of leaflets FL, SL while enabling it to follow the movement of the second leaflet SL. In this way, with the change of the cardiac cycle, the second coaptation surface **41***b* facing the second leaflet SL maintains coaptating the second leaflet SL, and the first coaptation surface **41***a* facing the first leaflet FL periodically coaptates and separates from the first leaflet FL with the pad **41** following with the movement of the second leaflet SL.

[0201] The pin may be integrally formed with the pad, or the two may also be two independent members, which is not specifically limited in the present disclosure.

[0202] FIG. **16** is a schematic structural diagram showing at least a portion of a medical device **50** according to further another embodiment of the present disclosure. FIG. **16** illustrates a state that the medical device **50** is implanted at a heart valve of a patient.

[0203] The medical device **50** has many same or similar elements with the medical devices **10**, **30**, **40**. For the purpose of conciseness, related descriptions are appropriately omitted. It may be understood that, on the premise that no contradiction occurs, elements of the medical device **50** and the medical device **10**, **30** and **40** may be combined with each other.

[0204] Referring to FIG. **16**, the medical device **50** includes a pad **51** and a support member **54**. The pad **51** has a first coaptation surface **51***a* and a second coaptation surface **51***b* which are configured to face the first leaflet FL and second leaflet SL respectively.

[0205] When the medical device **50** is implanted in the patient's heart, the pad **51** is rigidly connected to the support member **54** (that is, connected in a manner preventing relative movement), and thereby maintaining the pad **51** at a preset position between the leaflets FL, SL and keeping the second coaptation surface **51***b* coaptating the second leaflet SL. This preset position is configured such that the first coaptation surface **51***a* is able to periodically coaptate and separate from the first leaflet FL with the movement of the first leaflet FL.

[0206] In this implementation, since the pad **51** is maintained at the preset position between the leaflets FL, SL with the second coaptation surface **51***b* coaptating the second leaflet SL, so that the pad **51** will obstruct the movement of the second leaflet SL, and thus the second leaflet SL loses its native physiological function.

[0207] Compared with the aforementioned implementations, if the medical device according to this implementation is adopted, after a long service time, the structure and function of the second leaflet may be adversely affected.

[0208] In the related art, a current implant, including its support structure, often affects the structure of an existing valve while repairing and improving closure of the valve, and thereby resulting in some hemodynamics and/or clinical issues. After the implant being implanted into the patient's heart, the patient usually needs to go to the hospital regularly for follow-up examination. In general, there are two aspects of purposes of a regular follow-up examination. On one aspect, it is to observe the effect of the implant on the cardiac function (whether it has improved, and the like) and the operating condition of the implant to determine whether there are any adverse events associated with the implant. On the other hand, it is to check the overall condition of the patient, such as heart failure and the use of the medicine, and

the like, so that it is determined whether the condition of the patient is effectively improved or whether further deterioration occurs. These follow-up examinations are generally required to be performed in the hospital (or clinic). Frequent follow-up examinations, especially for a patient in remote areas, will cause the economic burden and time cost of the patient to be increased. At the same time, since the follow-up time has a relatively long interval, the change of the condition is often unpredictable, and thereby making it more difficult to achieve the goals of identifying problems early, preventing the condition from worsening and improving the quality of life for patients.

[0209] To solve the aforementioned problems, the embodiments of the present disclosure provide a cardiac implant. A cardiac implant **100** according to an embodiment of the present disclosure will be described with reference to FIGS. **17** and **18** below. FIG. **17** is a schematic structural diagram of the cardiac implant **100**, and FIG. **18** illustrates a schematic structural diagram of the cardiac implant **100** when it is implanted at a patient's heart valve.

[0210] It should be noted that, in the drawings of the present disclosure, the valve is located between a first chamber and a second chamber. The valve periodically allows blood to flow from the first chamber to the second chamber while preventing flowing in the reverse direction. The valve includes a pair of leaflets FL, SL match with each other.

[0211] Specifically, the valve may be a mitral valve. Correspondingly, the first chamber may be the left atrium, the second chamber may be the left ventricle, and one of the pair of leaflets FL, SL is the anterior leaflet and the other is the posterior leaflet. It may be understood that, the cardiac implant provided by the present disclosure is not limited to the application in mitral valve, but may also be applied to other heart valve (for example, a tricuspid valve), in this case, the heart valve includes three leaflets.

[0212] Referring to FIG. **17** and FIG. **18**, the cardiac implant **100** (a medical device) includes a treatment device **110** and a pair of sensors **120***a*, **120***b*. It may be understood that, in other examples, the cardiac implant **100** may include only one sensor or three or more sensors. The treatment device **110** is configured to repair a function of the valve to prevent blood from flowing from the second chamber back to the first chamber. The implementation of the treatment device **110** will be described in detail below. The pair of sensors **120***a*, **120***b* are attached to the treatment device **110** and are configured to sense physiological information of the patient.

[0213] In an example, the physiological information may include, but is not limited to, one or more type of the following: blood pressure information, blood flow velocity information, blood pH information, blood temperature information, blood oxygen level information, electrocardiographic information, heart sound information, cardiac acceleration information and cardiac contractility information of the patient's heart. Correspondingly, the sensors in the present disclosure may include any sensing device that is capable of sensing one or more type of the above-mentioned information.

[0214] The cardiac implant provided by the present disclosure is not only able to improve the regurgitation of the patient for realizing a therapeutic purpose, but also is able to sense the physiological information of the heart of the patient for realizing a monitoring purpose. By using the cardiac implant provided by the present disclosure, the patients may need to visit the hospital for follow-ups less frequently or not at all. Consequently, the cardiac implant provided by the present disclosure is able to effectively reduce the financial burden and time cost for the patient. Furthermore, in the present disclosure, at least one sensor is positioned in the patient's heart by attaching to the treatment device rather than being directly anchored to a tissue of the heart of the patient, and thereby harm to the tissue is reduced.

[0215] Referring again to FIG. **17** and FIG. **18**, the treatment device **110** includes a pad **111**. When the cardiac implant **100** is implanted in the patient's heart, the pad **111** is configured to be located between the pair of leaflets FL, SL. The pad **111** is configured to cooperate with the pair of leaflets FL, SL to enable the valve to be periodically opened and closed, and thereby allowing the blood to flow from the first chamber to the second chamber while preventing flowing in the reverse direction. Certainly, in an applications scenario of the tricuspid valve, the pad **111** may be configured to be located among three leaflets. A pair of collection devices (for example, sensors) **120***a*, **120***b* are attached to the pad **110** to facilitate fixing of the pair of collection devices **120***a*, **120***b*.

[0216] Referring again to FIG. **17** and FIG. **18**, the pad **111** includes a top surface **111***a* facing the first chamber and a bottom surface **111***b* facing the second chamber. The pair of sensors **120***a* and **120***b* may be a pair of pressure sensors **120***a*, **120***b*. The pair of pressure sensors **120***a*, **120***b* may be respectively attached to the top surface **111***a* and bottom surface **111***b* of the pad **111** to sense blood pressure information of the first chamber and the second chamber, respectively. In an example, sensing surfaces of the pressure sensor **120***a* and the pressure sensor **120***b* may face the first chamber and the second chamber, respectively. The sensing surface may include a vibrating diaphragm.

[0217] Sensing surfaces (for example, vibrating diaphragms) of the pair of pressure sensors **120***a*, **120***b* faces the first chamber and the second chamber, respectively, and are able to sense blood pressures in the first chamber and the second chamber of the entire cardiac cycle, respectively. This provides the doctor with hemodynamic information having diagnostic value. This information is critical for evaluating the overall cardiac function and the working condition of the valve and the cardiac implant **100**. Meanwhile, the pressure information is also able to assist the doctor in evaluating the placement position of the implant during the implantation process and making real-time assessment of whether there is any obstruction to the blood flow into the second chamber during diastole. Therefore, the success of the implantation operation is able to be better ensured, and a better clinical effect is achieved.

[0218] Additionally, when the valve opens, the blood flow that flows from the first chamber to the second chamber is able to nearly directly impact onto the pressure sensor **120***a* (on its vibrating diaphragm) attached to the top surface **111***a*. This allows the physiological information (that is, blood pressure information) sensed by the pressure sensor **120***a* to reflect whether the blood flow that flows from the first chamber to the second chamber is normal, so that it is able to relatively accurately reflect whether there is a stenosis issue with the valve of the patient after the cardiac implant **100** is implanted.

[0219] When the valve closes, if there is still the regurgitation that flows from the second chamber to the first chamber, the regurgitation will nearly directly impact onto the vibrating diaphragm of the pressure sensor **120***b* attached to the bottom surface **111***b*, so that the physiological information (that is, pressure information) and variations thereof sensed by the pressure sensor **120***b* due to the blood flow will reflect whether there is the regurgitation that flows from the second chamber to the first chamber.

[0220] It may be understood that, when the pressure sensor is configured to side face sideways to the first chamber and second chamber, the blood flow will impact the sensing surface of the pressure sensor from the side, so that the pressure response generated by the pressure sensor will be lower than the actual pressure of the blood flow. Conversely, when the pressure sensor is configured to face the first chamber and second chamber, the blood flow will directly impact onto the sensing surface, so that the pressure sensor is able to more accurately reflect the actual pressure of the blood flow.

[0221] Furthermore, as shown in FIG. **17** and FIG. **18**, the pair of sensors **120***a*, **120***b* are located at the middle position of the top surface **111***a* and bottom surface **111***b* of the pad **111** in the width and thickness directions of the pad, respectively. When the pair of pressure sensors **120***a*, **120***b* are arranged centrally on the pad **111** located between the leaflets of the valve, they are located at the central position of the blood flow path, at this position they are able to more accurately reflect the overall pressure of the atrium or ventricle, and thereby more accurately reflecting whether there is stenosis or regurgitation at the valves.

[0222] On the other hand, as illustrated in FIG. **18**, since the pair of pressure sensors **120***a*, **120***b* are attached to the top surface **111***a* and bottom surface **111***b* of the pad **111** respectively, while the leaflets of the valve are located on the sides of the pad **111**, therefore, the top surface **111***a* and the bottom surface **111***b* of the pad will not contact with the leaflets of the valve when the valve closes. Consequently, the leaflets are prevented from interfering with the pressure sensors **120***a*, **120***b*, so that the accuracy of the pressure sensors **120***a*, **120***b* sensing the blood pressure is improved, and thus whether there is stenosis or regurgitation at the valve is more accurately and more timely reflected.

[0223] Consequently, by using the pair of pressure sensors **120***a*, **120***b* respectively attached to the top surface **111***a* and the bottom surface **111***b* of the pad **111**, whether the valve has stenosis or regurgitation issues after the cardiac implant **100** is implanted is able to be reliably detected, so that a more accurate assessment of the patient's postoperative recovery and development of the condition of the patient is able to be accurately monitored.

[0224] It should be noted that, although in the foregoing embodiments, the cardiac implant **100** includes the pair of sensors **120***a*, **120***b*, in other implementations, the cardiac implant **100** may include merely the sensor **120***a* attached to the top surface **111***a*, or may include merely the sensor **120***b* attached to the bottom surface **111***b*. Certainly, in other examples, the cardiac implant **100** may include more sensors.

[0225] It should also be noted that, although in the foregoing embodiment, the pair of sensors **120***a*, **120***b* are respectively attached to the top surface **111***a* and the bottom surface **111***b* of the pad **111**, in other examples, the pair of sensors **120***a*, **120***b* may also be attached to other portions of the pad **111**. For example, in some examples, one or more sensors may be attached to the sides of pad **111**. In other examples, for example for a pad having the structure shown in FIG. **7**, one or more sensors may be attached to a portion of the top surface **512** of the pad **111** close to the first coaptation surface **511** such that the sensor is located in an intermediate position of the two leaflets.

[0226] Continuing referring to FIG. **17** and FIG. **18**, the pad **111** further includes a pair of coaptation surfaces **111***c*, **111***d*. The pair of coaptation surfaces **111***c*, **111***d* are configured to face the pair of leaflets FL, SL, respectively. As the cardiac cycle changes, each coaptation surface of the pair of coaptation surfaces **111***c*, **111***d* periodically coaptates and separates from the leaflet it faces, and thereby enabling the valve to be periodically opened and closed. Specifically, when one of the coaptation surfaces **111***c*, **111***d* coaptates its corresponding leaflet, a coaptation length between them may range from 6 mm to 12 mm. That is, a length of the coaptation surfaces **111***c*, **111***d* may also range from **6** mm to **12** mm. In particular, the leaflet FL may be the anterior leaflet, and the leaflet SL may be the posterior leaflet, and the pad **111** is configured to be closer to the leaflet SL than to the leaflet FL. Specifically, the coaptation surfaces **111***c*, **111***d* may be smooth transition curved surfaces to reduce resistance to the blood flow.

[0227] When the second chamber is in the diastole, the pair of leaflets FL, SL move away from each other to form passages between the pair of leaflets FL, SL and the pair of coaptation surfaces **111***c*, **111***d*, respectively. At this time, the valve opens to allow the blood flow to pass through these passages from the first chamber into the second chamber. When the second chamber is in the systole, the pair of leaflets FL, SL move toward each other to make the pair of leaflets FL, SL coaptate the pair of coaptation surfaces **111***c*, **111***d*, respectively. At this time, the valve closes to prevent the blood flow flowing from the second chamber back to the first chamber. It should be noted that, in the present disclosure, when a leaflet coaptates a coaptation surface, the leaflet and the coaptation surface may be in contact with each other to prevent the blood flow from flowing therebetween.

[0228] In this implementation, the pad **111** does not affect or minimally affects the movement of the pair of leaflets FL, SL, so that the pair of leaflets FL, SL are able to maintain their original physiological functions. That is, in this implementation, as the cardiac cycle changes, the pair of leaflets FL, SL are able to naturally and periodically move toward and away from each other. Therefore, by using the treatment device according to this implementation, there will be minimally or even no adverse effects on the structure and function of the pair of leaflets FL, SL. In other words, the cardiac implant **100** provided by the present disclosure has no restriction or hindrance on the natural movement (closing, opening) of the valve, and it is not associated with the supporting structure of the valve, so that the corresponding adverse effect is avoided.

[0229] Continuing referring to FIG. **17** and FIG. **18**, the treatment device **110** may also include a support member **112**. After the cardiac implant **100** is implanted into a patient's heart, the support member **112** is located in the first chamber and is connected to the pad **111**, and thereby positioning the pad **111** between the pair of leaflets SL, FL. By means of the support member **112** located in the first chamber, the pad **111** is able to be reliably positioned between the pair of leaflets FL, SL. In particular, the

connection position between the support member **112** and the pad **111** is configured to be adjustable to allow the position of the pad between FL and SL to be adjusted.

[0230] Continuing referring to FIG. **17** and FIG. **18**, the support member **112** may be annular in shape, and the pad **111** is centrally disposed on a side of the support member **112** along a first radial direction of the support member **112**, such that the pad **111** is centrally positioned between the pair of leaflets FL, SL of the valve. The length direction of the pad **111** is consistent with the first radial direction, and the width direction and height direction of the pad **111** are perpendicular to the first radial direction. Along the length direction of the pad **211**, the pad **211** has two side surfaces which are arc-shaped curved surfaces configured to fit with the leaflets. After the cardiac implant **100** is implanted into the patient's heart, the support member **112** may be placed at the valve annulus of the heart. In some embodiments, the support member **112** may have a mesh frame structure. During delivery, the support member **112** may firstly be folded to reduce its volume. After being delivered to a target position, it may be unfolded again.

[0231] It may be understood that, the implementation of the support member **112** is not limited to the above, as long as it is able to position the pad **111** between the pair of leaflets FL, SL of the valve. For example, in some embodiments, the support member **112** may also be semi-annular or partially annular in shape.

[0232] FIG. **19**A is a schematic structural diagram illustrating a cardiac implant **200** according to another embodiment of the present disclosure that is implanted in a patient's heart. The cardiac implant **200** is substantially the same as the cardiac implant **100**. For the sake of brevity, the similarities will not be repeated herein.

[0233] Referring to FIG. **19**A, the cardiac implant **200** includes a treatment device **210**. The treatment device **210** includes a pad **211** and a support member **212**. The pad **211** is substantially the same as the pad **111** in the aforementioned embodiment, and the support member **212** is substantially the same as the support member **112** in the aforementioned embodiment. Relevant descriptions of the pad **211** and the support member **212** may refer to the descriptions of the pad **111** and the support member **112** in the aforementioned embodiments.

[0234] The cardiac implant **200** also includes a sensor **220**. The sensor **220** is attached to the support member **212** and is configured to sense physiological information of the patient. In particular, the sensor **220** may be a pressure sensor. Specifically, the sensor **220** may be attached to a portion of the support member **212** closer to the body surface, such as closer to the anterior, left, or posterior chest wall. In particular, the sensor **220** may be attached to the support member **212**, and their relative positions may be configured such that the support member **212** is not located between the sensor **220** (at least the communication portion of the sensor **220**) and an external device in communication with the sensor **220**. In this way, interference from the support member **212** (especially when it is made of metal) on wireless communication between the external device and the sensor is minimized.

[0235] As shown in FIG. **19**A, the support member **212** has an upper side and a lower side along a direction from the first chamber to the second chamber. The upper side is farther from the pad **211** and closer to the first chamber compared to the lower side, and the lower side is closer to the pad **211** and closer to the second chamber compared to the upper side. An area between the upper side and the lower side is an intermediate region of the support member **212**. Both the sensor **220** and the pad **211** are located at the lower side that closer to the second chamber, and the sensor **220** is offset from the pad **211** in the radial direction of the support member **212**. It may be understood that, the support member **212** (or its main body portion) is generally annular (closed or unclosed) or has a circular surface facing the second chamber. Therefore, the orientation term "radial" in the present disclosure may be relative to this annular or circle.

[0236] Specifically, referring to FIG. **19**A, the sensor **220** and the pad **211** are offset from each other along the direction from one leaflet SL to the other leaflet FL, such that when the support member **212** is implanted between the leaflets of the valve, the sensor **220** is located between the leaflet SL and the pad **211**. The sensor **220** is a pressure sensor, and an end of the sensor **220** is fixed to a lower edge or a lower surface of the support member **212** (that is, the edge or surface on the lower side of the support member **212**), and the other end of the sensor **220** faces the second chamber, so that this facilitates sensing the pressure of blood flow that flows from the second chamber into the first chamber.

[0237] It may be understood that, the other end of the sensor **220** has a sensing surface. When the valve is closed, the sensing surface is located in a region formed by the lower side of the support member **212**, the leaflet SL and the pad **211** and faces the second chamber. This ensures that if regurgitation that flows from the second chamber to the first chamber exists between the leaflet SL and the pad **211**, the regurgitant will nearly directly impact on to the sensing surface of the sensor **220**, so that the sensor **220** detects pressure information due to the blood flow. By arranging the sensor **220** on the support member **212**, between the leaflet SL and the pad and the sensing surface facing toward the second chamber, the sensor is able to quickly and accurately sense the blood pressure caused by the regurgitation. If the sensor is set to be in other orientations (for example, facing the first chamber), it might not be able to, or would more difficult/slower to detect the regurgitation from the second chamber due to pressure and directional changes in blood flow. In the present embodiment, however, even there is minimal regurgitation between the first and second chamber, the sensor **220** may sensitively capture it.

[0238] It should be understood that, although merely one sensor **220** is shown in FIG. **19**A, the cardiac implant **200** may include a plurality of sensors **220**. The plurality of sensors **220** may be attached to different portions of the support member **212**. For example, one sensor **220** may be disposed at a lower edge of the support member **212** and between the leaflet FL and the pad **211**, and another sensor **220** may be disposed at the lower edge of the support member **212** and between the leaflet SL and the pad **211**. In the case that the valve is a tricuspid valve, there may be one sensor **220** disposed at the lower edge of the support member **212** and between the third leaflet and the pad **211**. Alternatively, some of the plurality of sensors **220** may be attached to the support member **212**, and others may be attached to the pad **211**.

[0239] In other examples, the sensor **220** may also be fixed to the intermediate region of the support member **212**, and a sensing surface of the sensor **220** faces the second chamber. In this case, a portion of the sensor **220** may be located

in the intermediate region of the support member **212**, and another portion extends beyond the lower side of the support member **212**, or the entire sensor **220** may be located at the intermediate region of the support member **212**. When the support member is an annular structure, the sensor **220** may also be located on an inner surface of the support member **212**. Compared to fixing the sensor **220** to the edge or surface of the lower side, fixing it to the intermediate region of the support member **212** is easier to implement and facilitates a stable connection between the sensor **220** and the support member **212**.

[0240] FIG. **19**B is a schematic structural diagram illustrating a cardiac implant **200'** according to another embodiment of the present disclosure that is implanted in a patient's heart. The cardiac implant **200'** is substantially the same as the cardiac implant **200**. For the sake of brevity, the similarities will not be repeated herein.

[0241] As shown in FIG. **19**B, the sensor **220'** may be fixed to the intermediate region of the support member **212**, or to an edge or surface of the upper side, or to an inner surface. Meanwhile, an end of the sensor **220'** has a sensing surface configured to face the first chamber to sense a blood pressure in the first chamber. It may be understood that, in this case, the sensor **220'** faces the first chamber and faces away from the second chamber, and therefore it is not subject to direct impact from the regurgitation. Compared to the blood pressure sensed by sensor **220**, the blood pressure sensed by sensor **220'** is more stable, and is able to more accurately reflect the overall pressure condition in the first chamber. Both sensor **220** and sensor **220'** may be simultaneously installed on the support member **212** to provide pressure information from different positions, so that the doctor is able to make more precise assessment of the patient's valve status, or the control unit shown in FIG. **12**A is able to control the adjustment mechanism to make more appropriate adjustments.

[0242] FIG. **20** is a schematic structural diagram illustrating a cardiac implant **300** according to another embodiment of the present disclosure that is implanted in a patient's heart. The cardiac implant **300** is substantially the same as the cardiac implant **100**. For the sake of brevity, the similarities will not be repeated.

[0243] Referring to FIG. **20**, the cardiac implant **300** includes a treatment device **310** and a pair of sensors **320***a*, **320***b*. The treatment device **310** includes a pad **311** having a top surface **311***a* and a bottom surface **311***b* that face the first chamber and the second chamber, respectively. The pair of sensors **320***a*,**320***b* may be a pair of pressure sensors **320***a*, **320***b*, and the pair of pressure sensors **320***a*, **320***b* may be attached to the top surface **311***a* and bottom surface **311***b*, respectively.

[0244] It should be noted that, in other examples, the cardiac implant **300** may include merely one of the pair of sensors **320***a*, **320***b*. It should also be noted that, in other examples, the sensors of cardiac implant **300** may be attached to positions on a place other than the top surface **311***a* and bottom surface **311***b*, such as be attached to the support frame. It should also be noted that, in other examples, the sensors of cardiac implant **300** may be sensors that are capable of sensing other physiological information.

[0245] The cooperation mode between the pad **311** and the pair of leaflets FL, SL differs from that between the pad **111** and the pair of leaflets FL, SL in the aforementioned embodiments. Specifically, the pad **311** includes a pair of coaptation surfaces **311***c*, **311***d*. After the cardiac implant **300** is implanted into the patient's heart, the pad **311** is configured to be located between the pair of leaflets FL, SL and follow the movement of leaflet SL, and the pair of coaptation surfaces **311***c*, **311***d* are configured to respectively face the pair of leaflets FL, SL. As the pad **311** follows the movement of leaflet SL, the coaptation surface **311***d* is configured to maintain coaptating the leaflet SL (for example, a coaptation length between them may range from 6 mm to 12 mm), and the coaptation surface **311***c* is configured to periodically coaptate and separate from leaflet FL. In other words, with changes in the cardiac cycle, the coaptation surface **311***d* remains in constant coaptate the leaflet SL, while the coaptation surface **311***c* periodically coaptates and separates from the leaflet FL.

[0246] In this implementation, the pad **311** does not affect or minimally affects the movement of the pair of leaflets FL, SL, so that the pair of leaflets FL, SL, particularly the leaflet FL, are able to maintain their original physiological functions. That is, in this implementation, as the cardiac cycle changes, the pair of leaflets FL, SL are able to naturally and periodically move toward and away from each other. Consequently, it may be seen that, this implementation has minimal adverse effects on the structure and function of the leaflets FL, SL.

[0247] There are many ways to position the pad **311** between the pair of leaflets FL, SL and to make the pad **311** move with the leaflet SL, which is not specifically limited in the present disclosure. As an example, continuing referring to FIG. **20**, the treatment device **310** also includes a pin **312** or other fixing member, this kind of fixing member is connected to the pad **311** and used for connecting the pad **311** to the leaflet. Specifically, the pin **312** may penetrate through the leaflet SL to attach the pad **311** to leaflet SL, and thereby locating the pad **311** between the pair of leaflets FL, SL and enabling it to follow the movement of leaflet SL. In this way, as the cardiac cycle changes, the coaptation surface **311***d* facing leaflet SL is able to maintain coaptating the leaflet SL, and the coaptation surface **311***c* facing leaflet FL is able to periodically coaptate and separate from the leaflet FL with the pad **311** following the movement of leaflet SL.

[0248] The pin **312** may be integrally formed with the pad **311**, and the two may also be two independent members, which are not specifically limited in the embodiments of the present disclosure.

[0249] Although the pad **311** in FIG. **20** is disposed on the leaflet on a side, the top surface **311***a* and bottom surface **311***d* of the pad **311** still face the first chamber and the second chamber, respectively. Consequently, the pressure sensors **320***a*, **320***b* on the top surface **311***a* and bottom surface **311***d* are also disposed to face the first chamber and the second chamber, respectively. Therefore, the blood flow will directly impact onto the pressure sensors **320***a*, **320***b*, so that the pressure sensors **320***a*, **320***b* are able to accurately reflect the pressure of the blood flow.

[0250] As shown in FIG. **20**, since the sensors **320***a*, **320***b* are attached to the top surface **311***a* and bottom surface **311***b* of the pad **311**, respectively, the sensor **320***a* is away from the leaflet SL in a manner facing the first chamber, and the sensing surface of sensor **320***b* is away from a distal end of the leaflet SL in a manner facing the second chamber, so that the pressure sensors **320***a*, **320***b* will not contact with the leaflets of the valve when the valve closes. This prevents the valve from interfering with the pressure sensors **320***a*, **320***b*,

and thereby the accuracy of the blood pressure sensed by the pressure sensors **320***a*, **320***b* is further improved.

[0251] FIG. **21** is a schematic structural diagram illustrating a cardiac implant **400** according to another embodiment of the present disclosure that is implanted in a patient's heart. The cardiac implant **400** is substantially the same as the cardiac implant **100**. For the sake of brevity, the similarities will not be repeated.

[0252] Referring to FIG. **21**, the cardiac implant **400** includes a treatment device **410** and a pair of sensors **420***a*, **420***b*. The treatment device **410** includes a pad **411** and a support member **412** for positioning the pad **411** between the pair of leaflets FL, SL. The support member **412** is substantially the same as the support member **112** in the aforementioned embodiments. The pad **411** has a top surface **411***a* facing the first chamber and a bottom surface **411***b* facing the second chamber. The pair of sensors **420***a*, **420***b* may be a pair of pressure sensors **420***a*, **420***b*, which may be respectively attached to the top surface **411***a* and bottom surface **411***b*. The difference lies in that the pad **411** is offset to a side of the support member **412**, and in addition, the connection between the support member **412** and the pad **411** is configured to be movable to allow the pad **411** to move with leaflet SL during the cardiac cycle.

[0253] It should be noted that, in other examples, the cardiac implant **400** may include merely one of the pair of sensors **420***a*, **420***b*. It should also be noted that, in other examples, the sensors of the cardiac implant **400** may be attached to positions on pad **411** other than the top surface **411***a* and bottom surface **411***b*. For instance, in some examples, the cardiac implant **400** may also include at least one sensor attached to the support member **412**, and the t least one sensor is disposed at a lower edge of the support member **412** and faces the second chamber, and radially offset from the pad **411** and disposed between the pad **411** and the leaflet FL. It should be noted that, in other examples, the sensors of cardiac implant **400** may also be sensors that are capable of sensing other physiological information.

[0254] The pad **411** also includes a pair of coaptation surfaces **411***c*, **411***d*. The pair of coaptation surfaces **411***c*, **411***d* are configured to respectively face the pair of leaflets FL, SL. After the cardiac implant **400** is implanted into the patient's heart, the pad **411** is rigidly connected to the support member **412** (that is, connected in a manner that prevents relative movement), and thereby maintaining the pad **411** at a preset position between the pair of leaflets FL, SL while keeping the coaptation surface **411***d* coaptating the leaflet SL. This preset position is configured such that the coaptation surface **411***c* is able to periodically coaptate and separate from the leaflet FL with the movement of the leaflet FL, and the leaflet FL coaptates the coaptation surface **411***c* during the systole and achieves a certain coaptation length (for example, 6 mm~12 mm), so that effective closure of leaflets is increased, and thus the blood flow that flows from the second chamber to the first chamber is prevented. During diastole, the leaflet FL opens to allow the blood to flow from the first chamber through a passage between leaflet FL and the coaptation surface **411***c* into the second chamber. In particular, the pad **411** is configured to avoid causing stenosis during diastole due to an insufficient space between the leaflet FL and the coaptation surface **411***c*, such as by adjusting the thickness of pad **411** and/or its position relative to the leaflet FL.

[0255] In another embodiment of the present invention, a cardiac implant system **10** is also provided. Referring to FIG. **22**, the implant system **10** includes a cardiac implant **20** and an external device **30**. The cardiac implant **20** may be any one of the cardiac implants **100**, **200**, **300** or **400** described in the foregoing embodiments. The sensor **21** of the cardiac implant **20** has a wireless transmission unit **22** (for example, a transmission interface or a signal transmitter). The external device **30** includes a wireless reception unit **31**, an analysis unit **32** and an alarm unit **33** (for example, a buzzer, a flashing light, and the like) that are in communication connection with each other. The wireless reception unit **31** receives pressure value information from the wireless transmission unit **22** of the sensor **21**. The analysis unit **32** (for example, a controller, a monitor or a terminal device has an analysis function, such as a computer, a mobile phone, and the like) determines whether to send an alarm signal to the alarm unit **33** based on the pressure value information. Upon receiving the alarm signal, the alarm unit **33** issues an alarm message through any one or a combination of a pattern, text or sound to alert the doctor with the abnormal opening/closing conditions of the valve. Consequently, the doctor is able to track and determine the post-implantation conditions of the implant **20** based on the sensed pressure value information and promptly carry out the subsequent treatment.

[0256] Specifically, for the cardiac implants **100**, **200**, **300**, **400** or **500**, it may be configured such that when a pressure difference between the two sensors **120***a*, **120***b* (or between two sensors **320***a*, **320***b*, or between two sensors **420***a*, **420***b*, or between two sensors **520***a*, **520***b*) exceeds a preset threshold (for example, 5 mmHg) within a specified time period (indicating possible valve stenosis), the analysis unit **32** send an alarm signal to the alarm unit **33**. For the cardiac implant **200**, it may be configured such that when the change in the pressure value is greater than a preset threshold within a specified time period (indicating possible valve regurgitation), the analysis unit **32** send an alarm signal to the alarm unit **33**. This predetermined threshold may be determined based on pressure values obtained under normal valve closure conditions.

[0257] It should be understood that, although terms such as "first" or "second" may be used in the present disclosure for describing various elements (for example, the first chamber and the second chamber), but these elements are not limited by these terms, and these terms are merely used for distinguishing one element from another.

[0258] It should be noted that, the various specific technical features (elements) described in the above detailed embodiments may be combined in any suitable manner without contradiction. For example, the pad shown in FIG. **1** to FIG. **10** may has the adjustment structure illustrated in FIG. **12**A to FIG. **13**B, or may include the sensors depicted in FIG. **11** and FIG. **17** to FIG. **21**. To avoid unnecessary repetition, the present disclosure will not be further described in various possible combinations.

[0259] It should be understood that, in the embodiments of the present disclosure, "at least one" refers to one or more, and "a plurality of" refers to two or more. The term "and/or" describes the association relationship of associated objects, indicating that three relationships may exist. For example, "A and/or B" may represent a case where A exists alone, both A and B exist, and B exists alone.

[0260] It should be understood that, multiple members and/or portions may be provided by a single integrated member or portion. Alternatively, a single integrated member or portion may be divided into separate multiple members and/or portions. The use of "a" or "an" to describe a member or portion is not intended to exclude other members or portions.

[0261] The foregoing descriptions are merely specific implementations of the present disclosure, but the protection scope of the present disclosure is not limited thereto. Any person skilled in the art may conceive of modifications or substitutions within the technical scope disclosed in the present disclosure, and such modifications or substitutions should be covered by the protection scope of the present disclosure. Therefore, the protection scope of the present disclosure shall be subject to the scope defined by the claims.

What is claimed is:

1. A medical device for improving a function of a valve of a patient, comprising a pad, the pad being configured to be capable of being positioned among a plurality of leaflets of the valve to make the valve periodically open and close by cooperating with the plurality of leaflets.

2. The medical device according to claim **1**, wherein the plurality of leaflets comprises a first leaflet and a second leaflet, the pad has at least a first coaptation surface, the first coaptation surface is configured to face the first leaflet and periodically coaptate and separate from the first leaflet as the first leaflet and/or the second leaflet moves, and the first coaptation surface is a concave surface.

3. The medical device according to claim **2**, wherein the valve allows blood to flow from a first chamber to a second chamber and prevent flowing in a reverse direction, along a height direction of the pad, a cross-sectional area of the pad gradually increases from a bottom end to a top end of the pad, and the first coaptation surface is configured to gradually extend toward a side where the first leaflet is located in a direction trending towards the first chamber.

4. The medical device according to claim **3**, wherein the first coaptation surface has a first edge portion and a second edge portion respectively located at two opposite ends of the first coaptation surface, the first edge portion is located at the top end of the pad, the second edge portion is located at the bottom end of the pad, and an included angle formed between a tangent plane of the first edge portion and a tangent plane of the second edge portion ranges from 10° to 45°.

5. The medical device according to claim **3**, wherein the pad further comprises a second coaptation surface, and the second coaptation surface is configured to face the second leaflet and gradually extend toward a side where the second leaflet is located in the direction trending towards the first chamber.

6. The medical device according to claim **2**, wherein the valve allows blood to flow from a first chamber to a second chamber and prevents flowing in a reverse direction, the pad further has a top surface, the top surface is a convex surface configured to face the first chamber, an included angle formed between a tangent plane of a central portion of the top surface and a tangent plane of an edge portion of the top surface ranges from 10° to 45°, and the edge portion of the top surface is close to the leaflet.

7. The medical device according to claim **1**, wherein the valve allows blood to flow from a first chamber to a second chamber and prevents flowing in a reverse direction, the medical device further comprises a support member connected to the pad, the support member is configured to be located in the first chamber to position the pad among the plurality of leaflets, the support member has a main body portion and a pair of connecting portions, and the pair of connecting portions are configured to extend to two opposite sides of the pad along a width direction of the pad respectively and be connected to the pad.

8. The medical device according to claim **1**, wherein the pad comprises an expandable mesh frame, a cover covering an outer side of the mesh frame and a plurality of coaptation surfaces, and the cover is disposed at a top end of the pad without covering any of the plurality of coaptation surfaces.

9. The medical device according to claim **2**, wherein the pad is configured to move following the second leaflet, and the first coaptation surface is configured to periodically coaptate and separate from the first leaflet as the pad moves following the second leaflet; and the medical device further comprises a pressure sensor, the pad further comprises a second coaptation surface for coaptating the second leaflet, and the pressure sensor is disposed on a top surface of the pad and is closer to the first coaptation surface than to the second coaptation surface.

10. The medical device according to claim **9**, wherein the pad is configured to be attached to the second leaflet.

11. The medical device according to claim **9**, wherein the valve allows blood to flow from a first chamber to a second chamber and prevents flowing in a reverse direction, the medical device further comprises a support member connected to the pad, the support member is configured to be located in the first chamber and position the pad between the first leaflet and the second leaflet, and the pad is connected to the support member in a manner that allows the pad to move following the second leaflet.

12. The medical device according to claim **1**, further comprising:

an adjustment mechanism; and

a control unit configured to control the adjustment mechanism to adjust a dimension of the pad.

13. The medical device according to claim **12**, further comprising a wake-up unit configured to wake up the control unit based on a preset schedule.

14. The medical device according to claim **12**, further comprising a wake-up unit and a sensor, wherein the sensor is configured to sense a physiological information of the patient, and the wake-up unit is configured to wake up the control unit in response to the physiological information satisfying a preset condition.

15. The medical device according to claim **14**, further comprising a support member connected to the pad, wherein the support member is configured to be located in the first chamber to position the pad among the plurality of leaflets, the sensor is disposed on a coaptation surface of the pad along a thickness direction of the pad, and along a height direction of the pad, the sensor is closer to an end of the pad connected to the support member than to an end of the pad away from the support member.

16. The medical device according to claim **14**, wherein the valve allows blood to flow from a first chamber to a second chamber and prevents flowing in a reverse direction, the plurality of leaflets comprises a first leaflet and a second leaflet, the pad comprises at least a first coaptation surface configured to face the first leaflet and periodically coaptate

and separate from the first leaflet as the first leaflet and/or the second leaflet moves, and the sensor is disposed on the coaptation surface and is closer to a top end of the pad than to a bottom end of the pad.

17. The medical device according to claim **12**, wherein the pad comprises a pair of main body members, the pair of main body members are stacked along a thickness direction of the pad, each main body member has a free end and a connected end opposite to each other, the connected ends of the pair of main body members are pivotally connected, and the adjustment mechanism is configured to adjust a thickness of the pad by adjusting an opening degree between the pair of main body members under the control of the control unit.

18. The medical device according to claim **12**, wherein the pad comprises a pair of shells, an end of one shell is sleeved on an end of the other shell in the width direction of the shells, and the pair of shells cooperatively define an internal space; and the adjustment mechanism is configured to adjust an overlapping degree of the pair of shells under the control of the control unit to adjust a width of the pad.

19. The medical device according to claim **1**, adapted to be implanted into a heart, wherein the heart comprises a first chamber and a second chamber, the medical device further comprises at least one sensor, and the at least one sensor is configured to sense a physiological information.

20. The medical device according to claim **19**, wherein the at least one sensor is attached to the pad, and the pad and the at least one sensor are configured in at least one of the following manners:

- the pad having a top surface configured to face the first chamber, and the at least one sensor comprising a pressure sensor attached to the top surface of the pad to sense a blood pressure in the first chamber;
- the pad having a bottom surface configured to face the second chamber, and the at least one sensor comprising a pressure sensor attached to the bottom surface of the pad to sense a blood pressure in the second chamber.

21. The medical device according to claim **19**, wherein the pressure sensor is attached to a central position of the top surface of the pad or a central position of the bottom surface of the pad in a width direction and a thickness direction of the pad.

22. The medical device according to claim **19**, wherein the medical device further comprises a support member connected to the pad, the at least one sensor comprises a pressure sensor, and the pressure sensor is fixed to the support member.

23. The medical device according to claim **22**, wherein the pressure sensor is arranged in one of the following manners:

- at least a portion of the pressure sensor being disposed in an intermediate region of the support member;
- the pad and the pressure sensor being located on different sides of the support member;
- the pad and the pressure sensor being located on a same side of the support member and being staggered in a radial direction of the support member.

24. The medical device according to claim **22**, wherein the pressure sensor has a sensing surface, and the sensor is configured in one of the following manners:

- the sensing surface being configured to face the first chamber to sense a pressure of blood flow in the first chamber;
- the sensing surface being configured to face the second chamber to sense a pressure of blood flow entering the first chamber from the second chamber.

25. An implant system comprising the medical device according to claim **19** and an external device, wherein the at least one sensor comprises a wireless transmission unit, the external device comprises a wireless reception unit for receiving a pressure value information from the wireless transmission unit of the sensor, the external device further comprises an analysis unit and an alarm unit, and the analysis unit receives the pressure value information from the wireless reception unit and determines whether to send an warning signal to the alarm unit according to the pressure value information; and after the alarm unit receives the alarm signal, the alarm unit sends an alarming information.

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