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(54) **BAG FOR AT LEAST PARTIALLY ENVELOPING A HEART**

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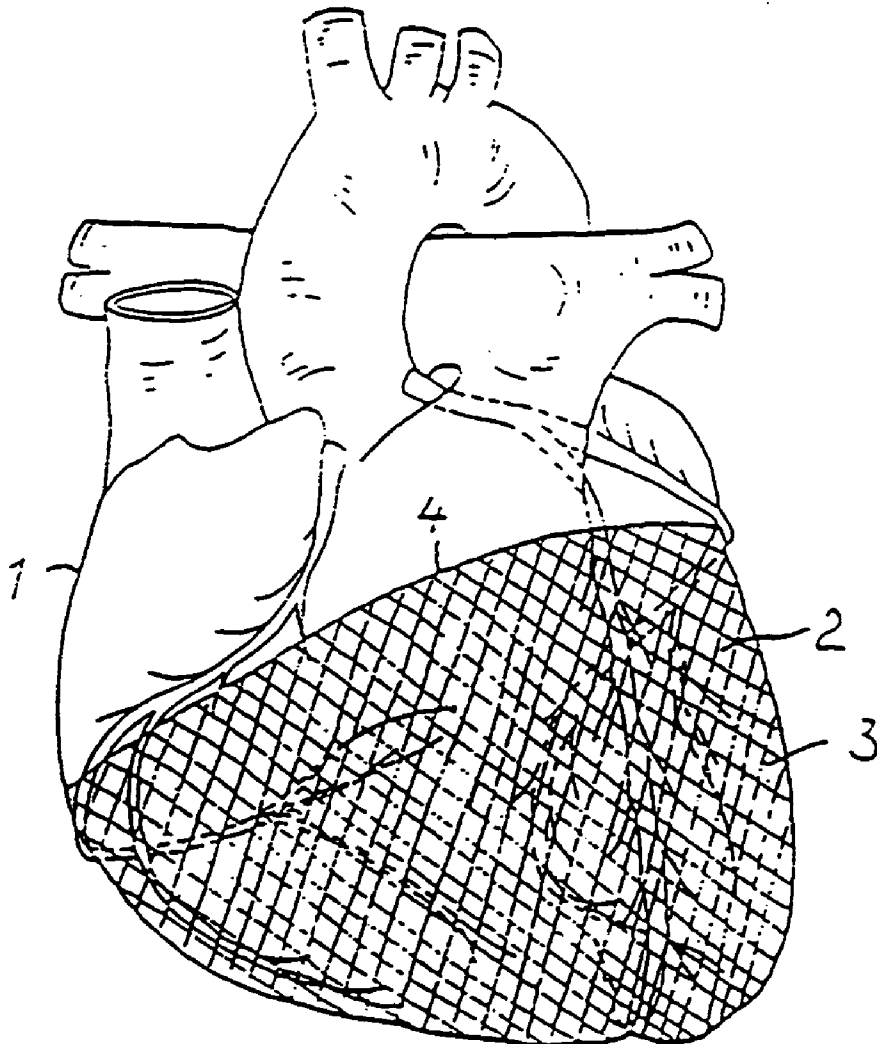
(57) **ABSTRACT**

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Related U.S. Application Data

(63) Continuation of application No. 10/140,225, filed on May 7, 2002, now Pat. No. 6,645,139, which is a continuation of application No. 09/453,722, filed on

A pouch to at least partly enclose a heart (1), the wall of the pouch (2) being elastic. The purpose of the pouch is to enclose at least part of a heart (1) and to oppose excessive dilation of the heart (1) that might be due to infectious disease of the heart muscle, for instance a viral infection or an autoimmune process. In many cases the use of such a pouch (2) may circumvent the need for a heart transplant.



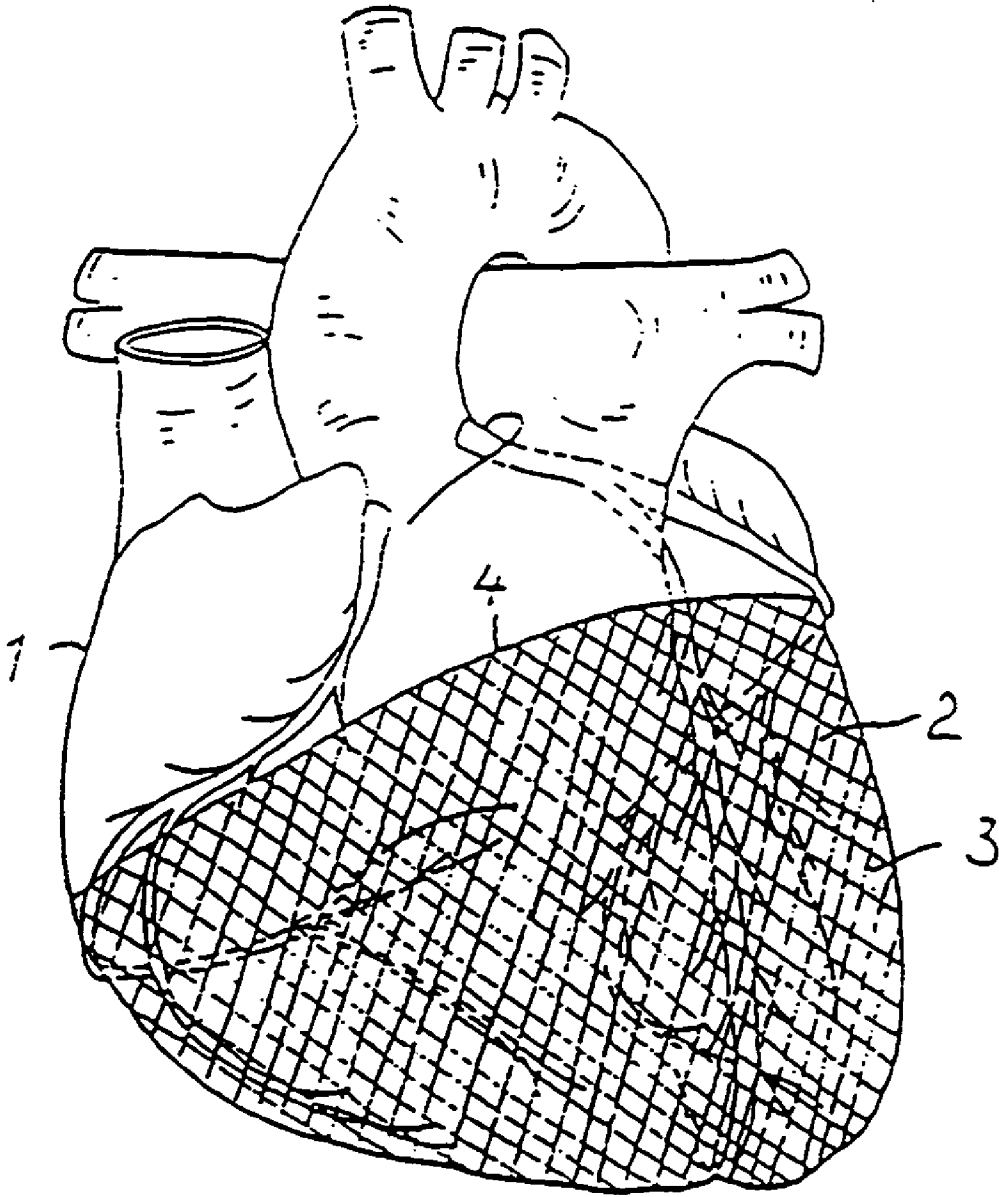
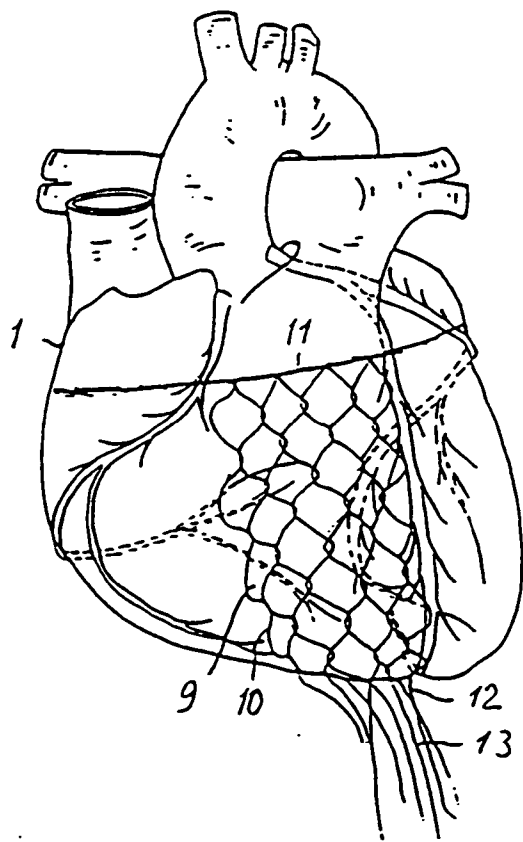
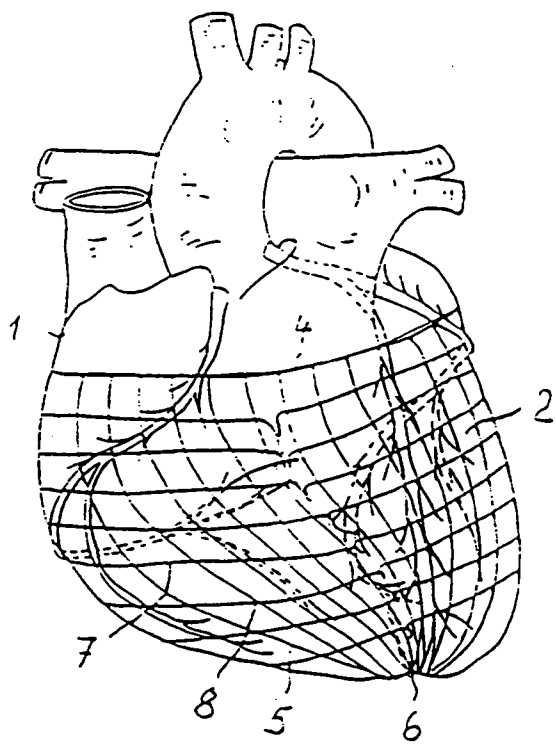


FIG. 1



BAG FOR AT LEAST PARTIALLY ENVELOPING A HEART

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of application no. PCT/EP98/03619, filed Jun. 16, 1998, which application claims the priority of German application no. 197 26 389.5, filed Jun. 21, 1997, and each of which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The invention relates to a bag, hereafter called pouch, with which to at least partly enclose a heart.

BACKGROUND OF THE INVENTION

[0003] Infectious disease of the heart muscle both by viral infection and by autoimmune processes may lead to enlarged heart volume. If such an enlargement exceeds a critical value, the result will be progressive heart dilation which can be explained by Laplace's law. As the volume subtended by the left heart chamber increases, the stresses in the walls of this cavity will increase. Consequently the muscle fibrils are overloaded and their ideal range of elongation is exceeded. When this excessive elongation takes place, there is, as a rule, a residual volume in the heart. Then the muscle fibrils must operate against a primarily high wall strain, and are further extended thereby. A vicious cycle arises, leading to increasing distension of the heart and consequent heart insufficiency.

[0004] It is basically feasible to treat such a development in its early stages by medicinally lowering the initial load by ACE inhibitors, however such treatment is not always successful. Moreover, on account of initially slight clinical effects, the status will be noticed many times only when a critical point already has been passed. In that case only a heart transplant can be resorted to.

[0005] The German patent document U1 295 17 393 discloses a pouch defined in the preamble of claim 1; this pouch however is inelastic and serves to prevent myocardial dilation by the end-diastolic pressure. While this known pouch does prevent cardiac wall distention, it delivers this effect impulsively once the heart volume equals the volume enclosed by the pouch. This impulsive effect adversely affects the heart. Moreover pleats may form in the pouch when the heart volume is less than that subtended by the size of the pouch.

OBJECTS AND SUMMARY OF THE INVENTION

[0006] The objective of the invention is to create a pouch with which to at least partly enclose a heart and opposing heart distention without thereby degrading heart function.

[0007] The problem basic to the invention is resolved by the disclosure of the characterizing part of claim 1.

[0008] The basic concept of the invention is to absorb in part the strains in the wall of the hollow body foremost constituted by the left heart chamber and to relieve thereby the myofibrils. This general effect alone already may prevent enlarging the heart volume beyond a critical value. Accordingly the pouch of the invention offers a support role.

[0009] The elasticity function of the invention may be implemented in a number of ways. A very simple implementation calls for the pouch always exerting the same force on the heart regardless of the pouch's elongation, as a result of which the heart, regardless of its volume, shall always be relieved at substantially the same strain. In another appropriate embodiment of the invention, the pouch wall is elastic, whereby the stress it exerts and hence the relief of the heart increases with volume. The characteristics of elongation may be altered depending on the desired relief. Appropriately for instance the pouch wall elasticity decreases with increasing stretching in order to account for the specific strain in the heart wall. Advantageously too, said stretching shall be bounded by a limit value at which the heart no longer can enlarge. Contrary to the known pouch, this limit value cannot be reached impulsively, but because of the elasticity of the pouch of the invention, can be reached only gradually, as a result of which impulsive pouch actions are precluded. The pouch limit value appropriately shall be at a pouch volume corresponding to the heart volume at maximum diastolic filling. On the whole, therefore, the kind of elasticity and the shape of the stretching curve of the pouch allows determining and adapting the myofibril relief implemented by this pouch.

[0010] To mount the pouch in place, it can be thorascopically opened and then be drawn over the heart muscle. This motion illustratively proceeds to the anulus fibrosus, that is, the valve plane, where the pouch shall be fixed in place.

[0011] In a further embodiment of the invention, the volume of the pouch in its unstretched state is less than the volume of the heart in the stage of minimum filling. As a result, the pouch shall reliably rest against the heart in all stretching phases.

[0012] If, as in one embodiment of the invention, the pouch wall is elastic and the stretching is bounded by a limit value, then advantageously the pouch shall be made of an elastic and of an inelastic material. In this case the elastic material determines the stretching function, whereas the inelastic material determines the stretching limit value. Appropriately in practice, the elastic material is made of a threaded sheet or fabric or knit into which are integrated threads made of a substantially inelastic material. The substantially spatially inelastic threads appropriately are longitudinally displaceable in the sheet or fabric or knit.

[0013] In this embodiment it is especially-advantageous that the substantially inelastic threads be guided segment-wise out of the pouch and in this manner are adapted at maximum diastolic filling by being segment-wise knotted in length and volume to the shape and/or volume of the pouch. In this process the substantially inelastic threads run appropriately from the edge of the pouch aperture to a substantially opposite tip of the pouch. The threads then can be guided out of the pouch in the zone of its tip.

[0014] As regards the embodiment wherein the pouch dilation is subject to a limit value, the pouch appropriately consists of a fabric or knit made of inelastic threads while however allowing bending and being crimped transversely to their longitudinal direction. This kind of shaping allows determining the stretching function and the limit value.

[0015] Appropriately the pouch wall is a thermoplastic allowing simple shaping of the pouch and adapting it to the

shape of the heart, or it may be made of a biological material, denatured bovine pericardium being especially suitable.

[0016] To implement permeability to gases, in particular oxygen, and to liquids, the wall of the pouch of the invention appropriately shall be a netting. Such netting appropriately may be made of an open-pore foam, for instance silicone foam. Such a foam assures highly uniform and gentle application of pressure to the heart muscle. Moreover such a foam is able to absorb a lubricant, for instance a serous liquid, thus providing good slippage between pouch and pericardium. Appropriately the lubricant is biological and genetically engineered, hyaluronic acid being especially suitable. By introducing a lubricant beforehand into the foam, good slipping properties are provided from the beginning and as a result primary, self-reinforcing irritation of the pericardium shall be avoided.

[0017] If the wall of the pouch of the invention is a netting, then such may be formed as a perforated sheet. Such a sheet is able to transmit the pouch pressure through a large surface to the heart.

[0018] The wall of the pouch of the invention also may be a fabric or a knit. In this manner the pouch's stretching behavior can be matched to any particulars within wide limits.

[0019] Regardless of the pouch wall netting being constituted by a sheet, fabric or knit, appropriately an additional coating of open-pore foam shall be provided to assure uniform force transmission and also holding any lubricants.

[0020] If the elasticity of the pouch wall decreases as stretching increases, or if there is a limit value on stretching, then a special embodiment of the invention provides that the pouch be composed of two kinds of plastic threads or fibers, one kind of higher, and preferably much higher shaping temperature than the other, one kind being elastic and the other kind relatively less, preferably much less elastic than the other. By using such differing fibers, it is possible to thermoplastically shape the pouch at a temperature at which the less elastic or inelastic material remains permanently shaped at a given shaping temperature, though not the more elastic material. The less elastic or inelastic material in this manner determines the maximum pouch stretching whereas the elastic material, which shall return to its initial shape, applies constricting forces on the heart, below the shape determined by the less or inelastic material.

[0021] In another embodiment of the invention, the plastic used in manufacturing the pouch is thermoplastic. This feature offers the advantage that not only can the pouch be prefabricated in simple manner into a given shape, but also that the pouch can be shaped during surgery, or its shape may be altered during surgery, in order to adapt the dimensions so found to the parts of the heart to be enclosed.

[0022] In a further embodiment of the invention the foam is made of silicone.

[0023] The objective of the invention furthermore is to propose a method for manufacturing a pouch as defined in claim 1. This problem is resolved by making a mold in the shape of the heart part to be enclosed and in that a gas-and/or liquid-permeable sheet or a netting of knit consisting of a thermoplastic is pulled over the mold while heated.

[0024] The structure of the mold appropriately is entailed or determined by imaging the shape of the heart to be enclosed and in that the mold is produced from this image. The image can be produced in arbitrary manner, for instance by x-rays or computer tomography.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The invention is elucidated further in relation to the drawings.

[0026] **FIG. 1** shows a first embodiment of the invention,

[0027] **FIG. 2** is a second embodiment of the invention, and

[0028] **FIG. 3** is a third embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0029] The drawing schematically shows a heart **1** partly enclosed by a pouch **2** of which the wall consists of a netting **3**. The pouch **2** reaches as far as into the zone of the anulus fibrosus, that is as far as the valve plane, where it is affixed (omitted from the drawing) to the heart muscle along a selvage **4**. The netting **3** consists of elastic threads. In the unstretched state, the volume of the pouch **2** is less than the volume of the heart **1** in the stage of minimum filling. As a result, the netting shall rest against the heart **1** in all stretching stages.

[0030] **FIG. 2** shows a second embodiment of the invention which is a variant of that of **FIG. 1**. Identical or corresponding components are denoted by identical references. The difference is that threads **5** converge from the selvage **4** into a central point **6**, whereas threads **7** run substantially circumferentially. Where they cross at points **8**, the threads **5** and **7** are connected to each other, either by being fused, bonded or by dipping the entire pouch **2** into a body of material, for instance foam which shall subsequently solidify.

[0031] **FIG. 3** shows an embodiment of a pouch **9** consisting of a knit of threads **10** running from a selvage **11** to a central point **12** where they are bundled away at their ends **13** which, following application of the pouch **9**, then can be tensioned or be knotted to one another in order to match thereby the pouch **9** to the shape and volume of the heart **1**.

1. A pouch (**2**) enclosing at least partly a heart (**1**) characterized in that the wall of the pouch (**2**) is elastic.

2. Pouch as claimed in claim 1, characterized in that the elasticity of the wall of the pouch (**2**) decreases with increasing stretching.

3. Pouch as claimed in claim 2, characterized in that the stretching is bounded by a limit value.

4. Pouch as claimed in claim 3, characterized in that the limit value is set at a pouch volume corresponding to the volume of the heart in the stage of maximum diastolic filling.

5. Pouch as claimed in claim 1, characterized in that the pouch volume in the stretched condition corresponds at a maximum to the volume of the heart in the stage of maximum diastolic filling.

6. Pouch as claimed in claim 3, characterized in that it is composed of elastic and of inelastic material.

7. Pouch as claimed in claim 6, characterized in that the elastic material consists of a sheet or a fabric or a knit consisting of threads into which are incorporated substantially non-elastic threads.

8. Pouch as claimed in claim 7, characterized in that the substantially inelastic threads are incorporated into the sheet or the fabric or knit in longitudinally displaceable manner.

9. Pouch as claimed in claim 8, characterized in that the substantially inelastic threads are guided each in by segment out of the pouch and thus are adjustable in length by means of segment-wise knotting and in that the volume and/or the shape of the pouch can be matched to the volume and/or the shape of the heart at maximum diastolic filling.

10. Pouch as claimed in claim 9, characterized in that the substantially inelastic threads run from the aperture edge of the pouch to a substantially opposite pouch tip.

11. Pouch as claimed in claim 10, characterized in that threads issue from the pouch in the vicinity of its tip.

12. Pouch as claimed in claim 3, characterized in that consists of a sheet, a fabric or a knit comprising crimps, a pleat, accordion geometry or the like.

13. Pouch as claimed in claim 3, characterized in that it consists of a fabric or knit of inelastic but bending threads crimped transversely to their longitudinal direction, in particular in wavy and/or sig-zag manner.

14. Pouch as claimed in claim 13, characterized in that the crimps are thermally set.

15. Pouch as claimed in claim 3, characterized in that the pouch is made of a knit and in that the knit's threads are inelastic but bending.

16. Pouch as claimed in claim 1, characterized in that the wall of the pouch (2) consists of plastic or a biological material.

17. Pouch as claimed in claim 16, characterized in that the biological material is bovine pericardium.

18. Pouch as claimed in claim 1, characterized in that the wall is in the form of a netting (3).

19. Pouch as claimed in claim 18, characterized in that the netting (3) consists of open-pore foam.

20. Pouch as claimed in claim 18, characterized in that the netting (3) consists of a perforated sheet.

21. Pouch as claimed in claim 18, characterized in that the netting (3) consists of a fabric or a knit.

22. Pouch as claimed in claim 21, characterized in that the sheet or the fabric or knit is coated with open-pore foam.

23. Pouch as claimed in claim 2, characterized in that the pouch (2) consists of two kinds of thermoplastic threads or fibers, one kind of which is of a higher, preferably substantially higher shaping temperature than the other kind, the one kind being elastic and the other kind being relatively less elastic, preferably substantially less elastic.

24. Pouch as claimed in claim 23, characterized in that the plastic is a thermoplastic.

25. Pouch as claimed in claim 19, characterized in that the foam consists of silicone.

26. Pouch as claimed in claim 19, characterized in that the foam is a lubricant.

27. Pouch as claimed in claim 26, characterized in that the lubricant is a biological lubricant.

28. Pouch as claimed in claim 26, characterized in that the lubricant is genetically engineered.

29. Pouch as claimed in claim 28, characterized in that the genetically engineered lubricant is hyaluronic acid.

30. A method for manufacturing a pouch as claimed in claim 1, characterized in that a mold in the shape of the article intended to enclose the heart is manufactured and in that a gas- and/or a liquid-permeable sheet or a netting or a knit made of a thermoplastic is pulled over the mold and shaped while heated.

31. Method as claimed in claim 30, characterized in that the shape of the heart to be enclosed is imaged and in that the mold is made based on that image.

32. Pouch as claimed in claim 1, characterized in that the wall of the pouch is made of tetrafluoroethylene, in particular of open-pore polytetrafluoroethylene foam

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