(19) FEDERAL REPUBLIC OF GERMANY

GERMAN PATENT AND TRADEMARK OFFICE

(12) **Unexamined patent specification**

(10) **DE 198 57 887 A1**

(51) Intl. Cl.[7]:

A 61 F 2/24

A 61 F 2/02

DE 198 57 887 A1

(21) References: 198 57 887.3
(22) Application date: 15 Dec 1998
(43) Publication date: 6 Jul 2000

(71) Applicant:

Fraunhofer Corporation for the Advancement of Applied Research e.V., Munich, Germany (DE) 80636; Figulla, Hans-Reiner, Prof., MD, Jena, DE 07743; Ferrari, Markus, MD, D. Disc.Pol., Jena, DE 07747; Lang, Klaus, MD, Cospeda, DE 07751

(74) Representative:

PFENNING MEINIG & PARTNER, Dresden 01217

(72) Inventor:

Weber, Carsten, Engr., Jena, DE 07743; Damm, Christoph, Engr., Jena, DE 07743; Figulla, Hans-Reiner, Prof., MD, Jena, DE 07743; Ferrari, Markus, MD, Dr.Disc.Pol., Jena, DE 07747; Lang, Klaus, MD, Cospeda, DE 07751

(56) Citations:

DE	195 32 846 A1
DE	4,316,971 A1
US	5,855,601 A
US	5,540,712 A
US	5,411,552 A

The following information was extracted from documents submitted by the applicant

Examination request is provided in acc. with §44 of the Patent Act (PatG)

(54) Anchoring support for a heart-valve prosthesis and a method for its manufacture

(57) The invention concerns an anchoring support for a heart-valve prosthesis and a method for its manufacture. A shape-memory metal is used for the anchoring support (stent), with which the anchoring support together with a heart-valve prosthesis will be achieved, without performing serious operational intervention, through the aorta as far as the immediate vicinity of the heart and can be implanted there. According to the invention, the anchoring support for this is formed as a one-part body, which is made of rod-shaped elements that represent at least partially a lattice structure.

DE 198 57 887 A1

Description

The invention concerns an anchoring support (stent) for a heart-valve prosthesis, as well as a method for its manufacture, in which a shape-memory metal, also called a memory metal, is used in order to implant a heart-valve prosthesis without having to perform serious operational intervention with a complete opening of the thorax.

So, among other things, for example, it is known from DE 195 46 692 A1 to introduce a self-expanding heart-valve prosthesis with an anchoring support by means of a heart catheter system without opening the thorax through the opened aorta in the groin of a person and reaching the desired location, to position it in the vicinity of the heart, preferably in the region of the original heart valve, and to install it firmly there by self-expansion.

However, it has been shown that the principle of the solution indicated there to date cannot be practicably employed. Up to now, no way has been shown whereby an anchoring support for a heart-valve prosthesis could be folded up once into so small a state that it could be guided together with a catheter through the aorta and here, in particular, through the curve of the aorta to the heart. But such an anchoring support has additionally to be in a position in a second state to attain a size and shape with which it is ensured that the heart-valve function can be ensured for a sufficiently long time.

The proposal that can be drawn from DE 43 16 971 A1 has also been proven not to be practicable. A shape-memory material is to be used there that can be rolled up or widened at the replacement location. The carrier designated there as a heart-valve anchoring ring for an artificial heart valve is to be in a rolled-up state, as already stated, guided by means of a catheter to the heart and is applied there to the inside wall of the aorta upon heating due to the coiling of the anchoring ring, whereby an anchoring means is additionally made available for anchoring using an anchoring ring projecting outward.

This solution also could not be practicably used up to now because the helically coiled body still has too large a diameter to be able to be guided through the aorta to the heart with no problems. In addition, a corresponding device must be positioned extremely precisely when it is placed in the vicinity of the heart, because the openings of the coronary vessels should in no way be closed.

In addition, the solution proposed there has proven to be problematic regarding the increase in the danger of thrombosis.

Also, the use of balloon catheters for the application targeted here has shown no satisfactory results up to now, and so the system described in WO 91/17720 A1 cannot be used in practice either. At the same time, an element made of a plurality of metal wires placed together and curved is used, onto which a heart-valve prosthesis can be fastened and the balloon present with it on the catheter is mechanically stretched. The size required for this, however, is not sufficient for the spatial conditions actually existing in the aorta, and so a, appropriate operational intervention has not been able to be performed with success to date.

It is therefore a task of the invention to offer an anchoring support for a heart-valve prosthesis that is simple to manufacture and with which it is moved into a position to guide it together with a heart-valve prosthesis through the aorta as far as the immediate vicinity of the heart and there to implant it successfully.

According to the invention, this problem is solved with the features of patent claim 1 for the anchoring support and in the features of claim 12 for a method for manufacturing a corresponding anchoring support. Advantageous embodiments and further developments of the invention result from the features cited in the subordinate claims.

At the same time, the solution according to the invention derives from the known concept of using a shape-memory material and it is therefore proposed to use an anchoring support made of shape-memory metal, which can assume a stampable shape and size upon reaching a specific predeterminable transition temperature, which makes possible a secure hold, tightness of the heart-valve prosthesis, low danger of thrombosis, and the consideration of leaving the coronary vessel openings open. The anchoring support for a heart-valve prosthesis according to the invention is therefore constructed as a one-part body, which is shaped out of individual rod-shaped elements, which represent at least partially a lattice structure.

What is more, the thickness of the rod-shaped elements is selected to be as small as possible in order to ensure at one time sufficient strength and stability and for another thing to still accordingly keep the danger of thrombosis low. Therefore, the thickness of the rod-shaped elements in the area is between 0.3 and a maximum of 1 mm.

Thus it can be ensured that the body manufactured from a semi-finished product that consists of a shape-memory metal, can be pressed together or folded very small, for another thing, which upon positioning the body pressed or folded together can be reliably held through the aorta not to exceed a free cross-section of about 7 mm.

According to the invention, the anchoring support is manufactured out of a semi-finished product consisting of shape-memory metal, in which the structure proper with the rod-shaped elements is cut out or stamped out. A laser-cutting method is especially preferably imagined for cutting it out, with which it is moved into a position for the desired structure to be constructed very precisely and exactly in the relatively low wall thickness.

After the desired structure is constructed, the anchoring support is brought to the desired shape and size for the implanted state and at the same time, is stamped during heat treatment, taking into consideration the transition temperature to be employed, which will advantageously be in the range of about 37°C.

As a semi-finished product, a correspondingly constructed plate-shaped element, but preferably a tubular semi-finished product, can be used. For the case in which a plate-shaped element is used, this must not only be widened for stamping the desired shape and size, but also be correspondingly curved, at least approximately into a circular shape.

After stamping the shape and size of the anchoring support according to the invention, the heart-valve prosthesis can be fastened onto it. The heart-valve prosthesis can be pulled onto the anchoring support from the outside of one side and if necessary additionally sewn onto it, whereby this part of the anchoring support is shaped and sized so that the commissures of a biological heart-valve prosthesis are taken into account, which, for example, can be removed from a swine heart and be made available in a prepared shape. But such a heart-valve prosthesis can also be guided by the anchoring support and be fastened from the inside onto the correspondingly constructed lattice structure or curved element. In a similar manner, an artificial heart-valve prosthesis made of suitable material can also be used for this.

A nickel-titanium alloy can be used as a shape-memory metal, which is, for example, obtainable commercially under the name of Nitinol. After building the structure and stamping the desired shape and size in the implanted state, the anchoring support can be improved and smoothed by a known surface-treatment method, such as electropolishing for instance, so that the danger of thrombosis can thereby be counteracted.

With the anchoring support according to the invention, a lattice structure is built in which the rod-shaped elements are constructed as meandering in part, and in their alignment form at least one support ring, which can be placed as such in the implanted state on the inner wall of the aorta. But on the one or on a plurality of such support rings formed with rod-shaped elements, anchoring barbs can be constructed, which also consist of the shape-memory metal used. These anchoring barbs are adjusted, however, during stamping, to a position aligned radially outward, so that they are hooked in the implanted state in the inner wall of the aorta and the anchoring support can be accordingly be held securely and the hooking can additionally act as a tensile force for the expanded anchoring support.

It is advantageous if the anchoring barbs are stamped in different alignments, which respectively lie in opposite directions relative to the longitudinal axis at an angle not equal to 90°, so that secure anchoring in both possible directions of anchoring-support movement can be achieved. The anchoring barbs should exhibit a length of at least 1 mm and a maximum of 5 mm, so that complete transection of the inner aorta wall can be avoided.

If an anchoring support is used with more than one support ring, these support rings can be achieved by means of connecting pins between meanders disposed beside one another, which meanders are formed by the rod-shaped elements of the support ring.

The heart-valve prosthesis can be in contact with a closed circular ring disposed on the front side or on a ring formed from a polygon.

But the option also exists of constructing on this front side of the anchoring support three curved elements for fastening the heart-valve prosthesis. At the same time, these curved elements are in contact in the implanted state on the inner wall of the aorta. With the curved elements, greater elasticity is attained compared to a closed ring, upon self-expansion and at the same time an adjustment to the shape of the commissures of a heart-valve prosthesis.

Besides a tubular shape, the anchoring support according to the invention can also be constructed in the form of a polygon, whereby it makes at least eight corners available. The last-mentioned shape has an increased self-latching effect, because the corner edges and the rod-shaped elements used for connecting a plurality of support rings cannot be aligned parallel to the longitudinal axis of the anchoring support. Hence an increased shape-protection can be attained to securely hold the anchoring support in the aorta.

After fastening the heart-valve prosthesis to the anchoring support according to the invention, the two of them are pressed or folded together and are accommodated in a pocket, which is fastened to a catheter. At the same time, the pocket is connected to a cooling system, through which an accordingly cooled salt solution is conducted, so that the anchoring support is kept below the transition temperature.

The catheter can then be guided in a known shape on a wire through the aorta up to the immediate vicinity of the heart. After reaching the desired position and checking the position relative to the coronary-vessel openings, the protective cap can be removed or destroyed and upon reaching the transition temperature, is set in the desired shape and size for the implantation of the anchoring support due to the self-expansion, whereby, at the same time, the anchoring barbs are aligned and clamp onto the inner wall of the aorta.

Finally, the guide wire and catheter can be removed again and the heart-valve prosthesis assumes the function of the natural heart.

The invention will be explained in detail by way of example in the following, using embodiment examples.

Thus they show:

Fig. 1, an example of an anchoring support according to the invention, with a heart-valve prosthesis in an implanted shape and size and

Fig. 2, a lattice structure of an example of an anchoring support in a development view.

In the example shown in **Fig. 1**, the anchoring support offers two saw-tooth–shaped support rings **6** formed from rod-shaped elements **4**, which are connected to one another with connecting pins **3**. In addition, a sealing and fastening ring **1** for the heart-valve prosthesis **2**, which exhibits a circular shape here, is available, as well as further rod-shaped elements, which represent the connection to the support rings **6** and take into account the shape and size of the commissures of the heart-valve prosthesis.

In addition, additional anchoring barbs **5** are available on the support rings **6** which, as has already been stated in the general part of the description, are aligned radially outward upon exceeding the pre-determined transition temperature during stamping.

In the example shown in **Fig**. **2** of an anchoring support according to the invention, the presentation of a development is selected in order to be able to more clearly recognize the structure constructed in the shape-memory metal. In this example, in turn, two support rings **6,** are selected using a saw-toothed construction for the rod-shaped elements **4**, on which, in turn, anchoring barbs **5** are available. Both of the support rings **6** are connected as well to connecting pins **3**, which are partially curved away, loop-like, for a required variable length, if necessary.

In the area of the anchoring support, on which the heart-valve prosthesis will be positioned and affixed, three curved elements **7** are constructed in this example, with which the heart-valve prosthesis can be in contact and be fastened. The shape of the curved elements **7** takes into account the shape and size of the commissures of a biological heart-valve prosthesis.

Claims

1. A anchoring support for a heart-valve prosthesis, which is formed from a shape-memory metal assuming a specific shape at a pre-determined temperature, **characterized in** that the anchoring support is a one-part body, which is formed out of rod-shaped elements (**1, 3, 4, 5**), which represent at least partially a lattice structure.

2. The anchoring support according to claim 1, characterized in that the rod-shaped elements (**4**) are constructed saw-toothed and form at least one support ring **(6)**.

3. The anchoring support according to claim 1 or 2, characterized in that anchoring barbs (**5**), which are aligned radially outward upon reaching the transition temperature of the shape-memory metal, are on the support ring(s) (**6**).

4. The anchoring support according to one of claims 1 through 3, characterized in that the anchoring barbs (**5**) exhibit a length of at least 1 mm.

5. The anchoring support according to one of claims 1 through 4, characterized in that the anchoring barbs (**5**), which are aligned radially outward relative to the longitudinal axis of the anchoring support in opposite directions, are at an angle not equal to 90°.

6. The anchoring support according to one of claims 1 through 5, characterized in that the support rings (**6**) are connected by means of connecting pins (**3**).

7. The anchoring support according to claims 1 through 6, characterized in that on the side on which the heart-valve prosthesis is affixed, three curved elements (**7**) are constructed for affixing the heart-valve prosthesis (**2**), which are in contact with the inner wall of the aorta.

8. The anchoring support according to one of claims 1 through 7, characterized in that all the elements (**1, 3, 4, 5**) exhibit a width/diameter of 1 mm maximum.

9. The anchoring support according to one of claims 1 through 8, characterized in that the lattice structure is constructed taking into consideration the size and position of the coronary vessel openings.

10. The anchoring support according to one of claims 1 through 9, characterized in that the anchoring support(s) is(are) disposed within a cooled pocket on a catheter during positioning through the aorta.

11. The anchoring support according to one of claims 1 through 10, characterized in that the support ring(s) (**6**) is(are) constructed like a polygon, with at least eight corners.

12. A method for manufacturing an anchoring support according to one of claims 1 through 11, characterized in that

- a lattice structure with rod-shaped elements (**1, 3, 4, 5**) is constructed in a semi-finished product made of shape-memory metal;
- the anchoring support in the desired shape and size is brought into an implanted position and this is stamped to the shape-memory metal during heat treatment, taking into consideration the transition temperature.

13. The method according to claim 12, characterized in that the lattice structure is constructed by

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.