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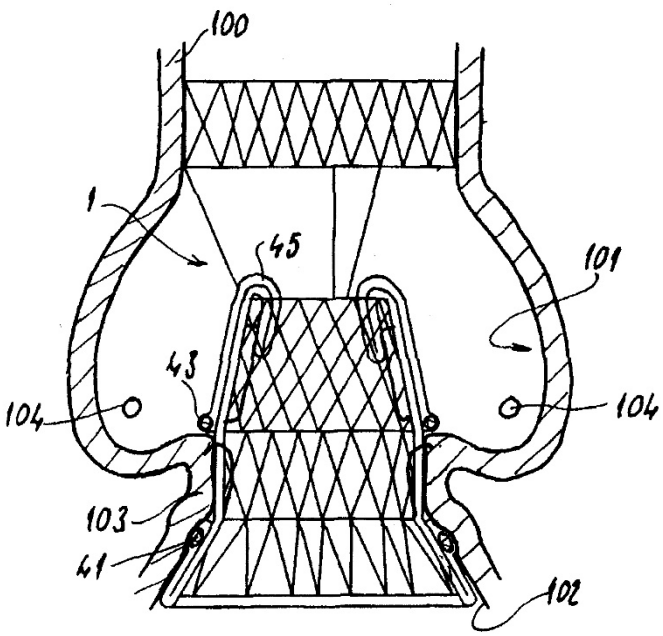
(54) Title: KIT ENABLING A PROSTHETIC VALVE TO BE PUT INTO PLACE IN A DUCT IN THE BODY



(57) Abstract: The kit (I) comprises a prosthetic valve (4) which is to be implanted and a stent (2). According to the invention, the valve (4) and the stent (2) are made in such a way that when the stent (2) is expanded, the valve (4) is situated outside the zone(s) (10, 11, 14) of the stent (2) which are to be expanded.

For an explanation of the two-letter codes and the other abbreviations, please refer to the "Guidance Notes on Codes and Abbreviations" at the beginning of each regular edition of the PCT Gazette.

KIT FOR PLACING A PROSTHETIC VALVE IN A DUCT IN THE BODY

The present invention relates to a kit for placing a prosthetic valve in a duct in the body, especially a heart valve, and in particular an aortic valve.

Documents WO 91/17720, WO 98/29057 and EP 1 057 460 each describe such a kit, comprising:

- the prosthetic valve to be implanted;
- a radially expandable framework, called a “stent,” which is able, in the expanded state, to bear against the wall of the body duct to be fitted with the valve, this bearing making it possible to immobilize this stent with respect to this wall; and
- means for fixing the valve to the stent.

The placement of the stent thus permits mounting of the valve in the body duct, eliminating the need for an external access route and, thus, a direct surgical intervention.

However, major drawbacks of this technique are that it entails a risk of the valve being damaged by the balloon used to expand the stent, and it limits the force of expansion that can be imparted to the stent. This limitation has repercussions on the anchoring of the stent, making a displacement of said kit possible. This limitation also has repercussions on the leaktightness of the stent in the area of the valvular ring which is particularly affected when calcified zones give the valvular ring an irregular form and/or a certain rigidity.

Another drawback of the prior art technique is that of directly joining the commissures of the valvules to the stent. The result of this is that an expansion of the stent, and thus of the valve, different than that intended may cause poor coaptation of the valvules and, consequently, defective functioning of the valve. The stent, therefore, has to undergo a predetermined expansion, which prevents or complicates adaptation of this stent to the anatomical variations.

In the case of implantation of an aortic valve, the prior art technique also has drawbacks in that it necessitates very exact positioning of the stent in the aorta so that the valve is located opposite the natural valvular ring, and it entails a risk of blocking the apertures of the coronary arteries that open out at the coronary ostia.

The present invention aims to overcome these various drawbacks.

The kit according to the invention comprises, in a manner known per se:

- the prosthetic valve to be implanted;

- a radially expandable framework, called a stent, comprising at least one zone intended to be expanded to allow this stent, in the expanded state, to bear against the wall of the body duct to be fitted with the valve, this bearing making it possible to immobilize this stent with respect to this wall; and

- means for mounting the valve with respect to the stent, making it possible to connect the valve to the stent in such a way that the placement of the stent allows the valve to be mounted in the body duct,

- expansion provided means such as a balloon catheter being to trigger the expansion of the stent at the implantation site.

According to the invention, the valve and the stent are designed in such a way that, at the moment when the stent is expanded, the valve is situated outside the zone or zones of the stent which are subjected to said expansion means.

The invention thus consists in separating the valve and said zone or zones to be expanded, so that the expansion of the stent can be effected with a force suitable for perfect anchoring of this stent in the wall of the body duct to be fitted with the valve, and without any risk of destruction or damage of the valve.

According to one possibility, the stent comprises a zone for mounting of the valve, which zone is distinct from the zone or zones of the stent to be expanded, and said mounting means connect the valve to this mounting zone.

The expansion of the stent thus triggers the deployment of the valve.

According to another possibility, said mounting means are designed in such a way that the valve is axially movable with respect to the stent between a position of non-implantation, in which it is situated outside the zone or zones of the stent which are to be expanded, and a position of implantation, which it can reach after expansion of the stent in the body duct, in which it is immobilized axially with respect to the stent.

The valve can thus form a subassembly separate from the stent prior to placement of this stent in the body duct, and it can be placed in the stent once the latter has been implanted. Alternatively, the valve is connected to the stent before said stent is placed in the body duct to be treated, and consequently it is introduced into this duct with the stent; said mounting means then comprise means of displacement so that, once the stent has been expanded, the valve can be displaced between said position of non-implantation and said position of implantation.

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