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(54) Titre : ENDOPROTHESES VASCULAIRES
(54) Title: VASCULAR STENTS

(57) Abrégé/Abstract:
The invention is directed towards a coating for medical implants, in particular, vascular stents, said coating comprising silicon dioxide, towards medical implants with a coating containing silicon dioxide and towards a method for their production. The coating can contain additional admixtures and have functionalisation coats. The substrate of the coating is produced from a durable material, preferably from a stainless steel.

Abstract

The invention is directed towards a coating for medical implants, in particular, vascular stents, said coating comprising silicon dioxide, towards medical implants with a coating containing silicon dioxide and towards a method for their production. The coating can contain additional admixtures and have functionalisation coats. The substrate of the coating is produced from a durable material, preferably from a stainless steel.

Vascular Stents

The invention under consideration is directed towards a medical implant, in particular, a vascular stent, for example, for implantation in the blood vessels of a body.

So-called "stents" are deployed in vessels at risk of occlusion, for the purpose of holding open vessels, such as blood vessels (in the case of arteriosclerosis). This can either be done by means of a catheter or by means of surgically opening the vessel, clearing it out where necessary and implanting the stent. Stents are generally cylindrical, tubular structures, for example, woven fabric tubes or pipe-like porous structures, that nestle against the inner wall of a vessel and hold open an unrestricted cross-section of the flow through which the blood in the blood vessel can flow freely.

Further uses of stents are in bile ducts, airways or the oesophagus. For example, stents are used in the treatment of carcinomas for the purpose of restricting the stenoses in the respiratory tract, bile ducts or oesophagus after dilatation has taken place.

Stents often consist of tubes with reticular walls that have a small diameter, because of which they can easily be brought to the destination by means of a catheter, where they can be expanded with the help of a balloon (balloon catheter) in the vessel by stretching the reticular wall of the stent to the necessary lumen and therefore the diameter necessary for supporting the vessel.

It is known to coat stents with plastics, such as polytetrafluoroethylene (PTFE; Teflon®), for example.

Inherent in known stents, however, is the problem that, because of their specific surface and their mesh structure, the body's cells often grow through or over the stents, which can, in turn, over the long run lead to a renewed occlusion of the vessel that had been secured with a stent. In this case, it is difficult to find the desired compromise between holding open the vessel and harmoniously integrating the stent into the organism. The conventional stent coatings are also not always flexible enough to go along with the stent's movements during implantation and expansion, which can result in damages to the coating. It has also been seen that an electronic potential can build up between the stent materials and the blood or other tissue, wherein such potentials can adversely modify the properties of the blood components in the layer bordering the stent materials, as a result of which uncontrolled deposits, such as plaques, can result. These problems are also found to some extent in other medical implants with similar requirements.

For this reason, there continues to be a need for medical implants, such as stents, for example, that allow easy implantation in the body of a patient.

This object is solved by the provision of a coating in accordance with independent Patent Claim 1, of a medical implant in accordance with independent Patent Claim 11 and of a method for the production of a coated medical implant in accordance with independent Patent Claim 20. Further advantageous embodiments , aspects and details of the invention under consideration result from the dependent patent claims and the description.

The object of the invention is to provide the medical implant, such as a vascular stent, with a coating containing silicon dioxide, or, in other words, a glass-like coating.

Accordingly, the invention is directed towards a coating for medical implants, said coating containing silicon dioxide. The silicon dioxide can be present in an amorphous or crystalline or semi-crystalline form.

The medical implant is preferably a vascular stent, for example, for blood vessels, bile ducts, oesophaguses or airways.

The properties of the coating can furthermore be modified by at least one admixture that is contained in the coating, wherein the admixture can be selected from aluminium oxide, titanium oxide, calcium compounds, sodium oxide, germanium oxide, magnesium oxide, selenium oxide and hydroxides, in particular, hydroxides of the previously mentioned metals. Particularly preferred admixtures are aluminium oxide and titanium oxide.

If an admixture to silicon dioxide is used, the ratio of the admixture to the total quantity of the coating can preferably be 0.5 to 50 % by weight.

In order to retain the desired surface properties across the entire surface of the medical implant, such as a vascular stent, it is preferred that the coating be essentially pore-free.

With specific embodiments, however, it can likewise be preferred that the coating have pores for functionalisation with additional substances, which are applied to the coating after the actual coating process and which deposit in the pores. Accordingly, the coating according to the invention can have an

additional functionalisation coat, even applied only partially or at selective points. Such a coat can correspond to the medical purpose of the medical implant and comprise an influencing of the growth of surrounding tissue, a killing off of unwanted tissue, building up a relationship between the medical implant and tissue, etc. The functionalisation coat can, for example, contain at least one medicine and / or at least one cell poison.

A major advantage of the medical implants according to the invention is to be seen in that the coating can be applied in an extremely thin layer, namely, preferably in the nano range, meaning in the range of single atom layers, which permits the final dimensions essentially to be selected during the production of the medical implant without it being necessary to take into account dimensioning changes caused by the coating that may not be predictable with precision. The thickness of the coating according to the invention is preferably 0.1 to 1000 nm, but it is understood that both thinner and thicker coatings are possible. Decisive in the selection of the layer thickness is the requirement that the coating not be damaged during the expansion of the implant in the body and that no additional pores be formed.

The coating can be applied in a single step, and thereby form a single layer, but can, in a preferred embodiment, also consist of multiple, successively applied layers. In the multi-layer method, the composition of each individual layer can be defined separately.

The invention is furthermore directed towards a medical implant that has a substrate that forms a basic structure and a coating applied to at least sections of the substrate, wherein this coating contains silicon dioxides or is made of silicon dioxides. In particular, the coating is a coating according to the invention given in the first aspect of the invention.

The medical implant is preferably a vascular stent. The vascular stent can be intended for a blood vessel, a bile duct, the oesophagus or the trachea, wherein it can be deployed for various types of animals, such as humans, pets and production animals.

The substrate is preferably constructed from a difficult-to-degrade material, whereby "difficult-to-degrade" is taken to mean a property in which the material shows no visible signs of degrading for at least one year after implantation in a body.

For medical implants, particularly vascular stents, the substrate can comprise customary materials, such as carbon, PTFE, Dacron, metal alloys or PHA, wherein steel alloys in particular are preferred materials.

The metal alloys that, according to the invention, can be deployed for the substrate are preferably selected from stainless steels.

A further preferred material for the substrate is a shape memory metal, in particular, nickel titanium alloys, which are used for stents because of their faculties for independent shape modification.

Ultimately, in a further aspect, the invention is likewise directed towards a method for the production of a medical implant, in particular of a medical implant according to the invention, said method having the steps:

- provision of a substrate forming the basic structure; and
- application of a coating containing silicon dioxide by means of a plasma coating method.

All that has been said with regard to the coating or the medical implant also applies analogously to the method according to the invention and vice versa, so that these are referred to alternately.

In order to obtain the desired pores for holding means of functionalisation in certain embodiments, it is furthermore preferred that the method comprises the step of producing the pores in the coating by means of neutron bombardment. For this purpose, neutron sources, such as particle accelerators, for example, can be used. A further variant for producing the function pores consists of manufacturing the pores by means of laser light.

The invention under consideration represents a coating for medical implants, in particular vascular stents, which, because of its inert, glass-like surface with silicon dioxide, largely prevents the growth of cells of the body or attachment of such cells, which, because of its hardness, counteracts damage when the implant is introduced into the body, therefore simplifying the handling, which, because of the thinness of the coating, permits a simpler design of the implant, has reduced friction as a result of low roughness levels and therefore a smaller impact on blood components and lower coagulation formation and in which there is no degradation of the coating whatsoever, even after a longer stay in the body.

Patent Claims

1. Coating for medical implants, said coating comprising silicon dioxide.

2. Coating according to Claim 1, characterised in that the medical implant is a vascular stent.

3. Coating according to Claim 1 or 2, characterised in that the coating contains an admixture that is selected from aluminium oxide, titanium oxide, calcium compounds, sodium oxide, germanium oxide, magnesium oxide, selenium oxide and hydroxides, particularly hydroxides of the previously mentioned metals, and mixtures of the same.

4. Coating according to Claim 3, characterised in that a ratio of the admixture to the total quantity of the coating amounts to 0.5 to 50 % by weight.

5. Coating according to one of the Claims 1 to 4, characterised in that the coating is essentially pore-free.

6. Coating according to one of the Claims 1 to 4, characterised in that the coating has pores for functionalisation.

7. Coating according to one of the Claims 1 to 6, characterised in that the coating contains an additional functionalisation coat.

8. Coating according to Claim 7, characterised in that the functionalisation coat comprises at least one medicine and / or at least one cell poison.

9. Coating according to one of the Claims 1 to 8, characterised in that the thickness of the coating is 0.1 to 1000 nm.

10. Coating according to one of the Claims 1 to 9, characterised in that the coating consists of multiple, successively applied layers.

11. Medical implant comprising a substrate that forms a basic structure and a coating that is applied to at least sections of the substrate and that contains silicon dioxide.

12. Medical implant according to Claim 11, characterised in that it is a vascular stent.

13. Medical implant according to Claim 11 or 12, characterised in that the coating is a coating according to one of the Claims 1 to 10.

14. Medical implant according to one of the Claims 11 to 13, characterised in that the substrate is constructed of a difficult-to-degrade material.

15. Medical implant according to one of the Claims 11 to 14, characterised in that the substrate comprises carbon, PTFE, Dacron, metal alloys, PHA.

16. Medical implant according to Claim 15, characterised in that the substrate comprises iron alloys.

17. Medical implant according to Claim 16, characterised in that the iron alloy is a stainless steel.

18. Medical implant according to Claim 14, characterised in that the substrate comprises a shape memory metal, in particular, nickel-titanium alloys.

19. Medical implant according to one of the Claims 12 to 18, characterised in that the vascular stent is intended for a blood vessel, a bile duct, the oesophagus or the trachea.

20. Method for the production of a coated medical implant, in particular of a medical implant according to one of the Claims 11 to 19, having the steps:

- provision of a substrate forming the basic structure; and
- application of a coating containing silicon dioxide by means of a plasma coating method.

21. Method according to Claim 20, characterised in that it furthermore comprises the production of pores in the coating by means of neutron bombardment or laser light.